

The Application of Advanced Technology to Orthopaedic Footwear Design

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Abstract

Orthopaedic footwear design has traditionally been a craft process. In service delivery, this poses problems of delays in production and inconsistency in quality of fit, function and cosmetic appearance. Advanced technology, in the form of techniques for measurement and computer-aided design (CAD) systems, is proposed to solve some of these problems. The thesis examines the clinical needs and analyses the application philosophy of such technology to related medical applications. The limitations of current understanding of technical requirements for plantar stress measurement are probed through experimental work to evaluate the effects of spatial resolution and threshold, and three case studies of interest in shoe insert prescription and design are presented. The design of shoe inserts requires consideration of both interface pressure and shape: a further study evaluates the basic information that is required to simulate aspects of the manual shaping process by a computer algorithm. The design of the shoe upper is another stage of vital importance to both fit and appearance. In the volume trade, CAD systems have been extensively developed: the potential to develop on from this established technology is explored via a trial involving the provision of computer-designed shoes for ten patients.

From the above investigations into aspects of footwear design, the stages of the integrated system are identified and considered with regards to their service and technology requirements. A description is given of the launch of an anglo-dutch project to develop such a system.

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CHAPTER 1. INTRODUCTION

1.1 BACKGROUND

Computer Aided Design and Manufacture for Body Support Systems

A body support system is a general term used to describe a medical appliance which interfaces mechanically to the body and provides external structural support.

Orthopaedic footwear can usefully be considered as a type of body support system, as can the sockets of artificial limbs, trunk supports and special seating which are other typical examples. Five years ago, computer-aided design and manufacture (CAD/CAM) related to body support systems was little more than a topic over which certain researchers enthused and industry showed polite if suspicious interest. Today, with CAD/CAM technology becoming firmly established in some areas of prosthetics and orthotics, the move into advanced technology is seen by many as inevitable for orthopaedic footwear over the long term. The real work of transferring technology into practical service options has begun.

The fundamental reason for introducing computer-aided processes into the body support area is to provide a tool for working with 3-dimensional surface contours. The support surfaces must mate with their respective body segment, and so are usually required to have a matching curved shape. They will often not be an exact inversion of the body shape but rather a related shape which provides a desirable features of load transference and other needs. In the established craft processes of today this process of shape generation is time-consuming and highly dependent on the training and interpretation of the individual worker. The primary objective of the introduction of a computer-based system would be to replace these methods with semi-automated processes which can provide a more rapid and repeatable result. This should theoretically achieve a more reliable product in a shorter time with lower labour costs, although the latter must be offset against higher capital costs of the equipment. Additional benefits often discussed include the possibility for digital storage of the shapes on computer discs, rather than handling for example bulky shoe lasts or plaster-casts: rapid retrieval of digital data for future re-working: more rapid and cheaper data transmission by disc or wire in preference to transportation of bulky models: enhanced training in prosthetics and orthotics by the use of quantifiable rectification processes and comparison of shapes; and gradual refinement of the

process by quantifiable analysis of the shape data taken with other clinical measures and outcome.

The output of the CAD/CAM process is either a *3-dimensional former* of the desired surface contour, eg. a positive of a prosthetic socket, or a set of *2-dimensional patterns* which will be used to construct the support eg. pattern pieces for surgical corset construction.

The technological developments which have enabled these concepts to move forward are both in computer systems, with the advent of microtechnology and particularly affordable workstations, and manufacturing technology, for example the development of computer-numerically controlled machinery. In industry the graphical potential of computers is exploited across a great breadth of industries, both medical and beyond. An awareness of these industrial systems and their modus operandi is essential to those wishing to engage profitably in CAD/CAM. Important examples of other applications, some medical, which should be considered in this context are listed here.

- fashion shoe trade - shoe uppers and shoe last design and manufacture (Smith, 1984; Flutter, 1983)
- garment industry - pattern design (Bell, 1987)
- medical imaging - 2 and 3-dimensional scanning, maxiofacial reconstruction (Moss et al, 1988), hip implants (Crawford et al, 1992)
- dentistry - dental prosthetic design (Duret & Blouin, 1986)
- car trade - body /seat design, particularly surface modelling & modification (Bezier, 1974) and interface pressure monitoring
- nuclear/offshore - remote handling and shape sensing
- sculpture - 3-D reprographics as in bust sculptures
- geology - stereophotogrammetry (Vergeest & Broek, 1987)

Prosthetic and orthotic applications are both considered in this background because of the close similarity and overlap of the CAD/CAM developments. The main application areas are lower and upper limb prosthetics, orthotic insoles, orthopaedic shoes, spinal orthoses and special seating.

History of Developments

CAD/CAM systems for design of lower-limb prosthetic sockets were the first of the type to come into service. Their main function is to provide for computer-based rectification of a measured stump shape into the required prosthetic socket shape. The

process was described by Saunders as one of *shape management*.. This comprises stages of shape capture, shape modification and shape reproduction leading to a 'measure-modify-manufacture' sequence of operation. Early systems were demonstrated following major projects at UCL Roehampton (Dewar et al, 1985.) and the Medical Engineering Research Unit (MERU) in Vancouver (Saunders et al, 1989), both of which have lead to commercial systems. The developments were both lengthy and expensive, since unfortunately no shape sensing hardware or shape reproduction machinery was available which came close to matching the needs for this specialised application. Additionally the developments were begun when the theories of surface modelling and graphical modification were in early stages: most of the serious graphical packages were only available on mainframe computers, and so were beyond the economic feasibility for application to prosthetics and orthotics. The knowledge gained from these first pioneering ventures and rapid advances in computer technology have facilitated a proliferation of other developments, both into scientific aspects such as ultrasonic measurement of soft tissue depths (Krouskop et al, 1987), and finite element modelling of modification procedures (Reynolds & Lord, 1992, Childress & Steege, 1987; Soh et al, 1990; Torres-Moreno et al, 1991) and of other systems at Seattle ('Shapemaker'), at Strathclyde ('MEX', indicating metafile executive), and in Texas (Krouskop et al, 1990).

Despite these computer-aided socket design systems reaching the market first, the original application envisaged for CAD/CAM was related to orthopaedic footwear. It is not surprising that this particular aspect of orthotics is now receiving renewed attention because of the high costs attached to orthopaedic footwear supply. Initially it was envisaged that the vast banks of shoe lasts which are routinely stored for many years could be replaced by storage on computer disks (Vickers & Foort, 1980). This would both save space and improved accessibility, providing for remote access by wire. This programme seemed to reach a hiatus, but interest in CAD/CAM for orthopaedic footwear was revived by developments in the volume shoe trade (Flutter, 1983; Smith, 1984). Substantial investments had been made into computer graphics systems for shoe upper design, and it was apparent that the same systems could be modified for use in the related orthopaedic shoe trade. One such system which adjusts the patterns in 2-D is now used at several sites across Europe ('Padsy', from Atom Vicam⁺). A full implementation of custom shoe design requires both the shoe upper patterns and the shoe last - the former over which the shoe is constructed- to be created. The Swedish company LIC Orthopaedics is now in clinical trials at four centres in Sweden and one in the UK with a shoe last design system, based on an

⁺ available through Standard Machinery, Evington Valley Road, Leicester.

optical foot shape scanner and matching & customisation of reference last models stored in the computer. In the USA a workshop was convened in 1986 under the joint sponsorship of the Veterans Administration, the National Institute for Health Research and NASA to define the requirements for an orthopaedic footwear system; the author attended and contributed a presentation on foot pressure measurements to the workshop. Subsequent to the workshop report, a project was developed at the State University in North Carolina, which has recently reported software developments for shoe last design (McAllister et al, 1991).

One area which has developed rapidly over the past few years, lead by commercial development, is the manufacture of orthotic shoe inserts by CAD/CAM. In one of the few scientific publications relating to this area, Staats et al (1989) describe an example technique which can be used for such a purpose. Shape capture is effected by taking a semi-load bearing impression of the foot followed by digitisation of a set of coordinates from the impression. Following surface modification, moulds for the orthoses are generated on CNC machinery. Insert fabrication may be by vacuum drape for the semi-rigid type, or by traditional fabrication using layers of plastics, rubber or cork. More recently, a project into CAD design of orthotic inserts has been launched as project 'INSCAD' under the european TIDE initiative, lead from University College London by Dr M Dewar. This project aims to incorporate both pressure and shape information into the design.

Various computer-aided systems are now proposed for the provision of special seating. Investigations conducted at Stanmore, UK, provide the beginnings of a theoretical basis to such design (Micheal & Walker, 1990): theoretical values based on measurement of soft tissue properties, buttock shape and using Finite Element modelling was substantiated by experimental results. A commercial system marketed by a leading prosthetics and orthotics company (Otto Bock[#]) can take a set of coordinates from a vacuum mould, model a surface through the points and then mill out a seat cushion at a central fabrication site. As this particular system stands, the central modification part of the measure-modify-manufacture sequence is not included, but the benefits of data transmission from clinic to central fabrication site are at present sufficient to encourage its adoption. Other systems use an interactive measurement device, where the shape capture is performed in an active seat which can be adjusted to give a preferred loading distribution, for example Brienza (1991). Thus the 'modification' is again achieved at the time of measurement, with the CAD/CAM system used to provide manufacture. The application of CAD/CAM in this particular

[#] Otto Bock UK, Englefield Green, Middlesex.

area of orthotics is complicated by the lack of concensus on requirements for shape & compliance, and the absence of a design methodology for specification of interface parameters in compliant structures. Some work is now reported in this area by Chung (1991), where the tissue and support materials were structurally modelled by finite element and other (not specified) analytic methods. The results of this modelling were compared with the experimental results obtained during CAD/CAM manufacture of seating, and the authors claim that this information proved useful in prescription of seating for significant decrease in the distorting uniaxial and shear stresses.

Computer systems have also assisted in the design of 2-D patterns for medical applications. St-Georges et al (1991) describe a system for thigh corset pattern generation. In industry, the Gerber-Camsco system is widely used for this type of application.

1.2 CLINICAL REQUIREMENTS FOR ORTHOPAEDIC FOOTWEAR

Foot Function in Shoes

Functional Anatomy of the Foot

The bony anatomy of the foot is dominated by the medial longitudinal arch, figure 1.1. The corner stone of this arch is the talus. Viewed from the medial border, the talus articulates with the calcaneus in the hindfoot. In the midfoot the arch is formed on the medial side by articulation of the talus onto the navicular, the navicular onto the three cuneiforms and thence respectively onto the base of the three medial metatarsals ie the 1st, 2nd and 3rd heads. The metatarsal heads terminate the arch, and articulate with the phalanges.

Viewed from the lateral border, the calcaneus articulates directly with the cuboid in the mid-tarsal region, the cuboid articulates with the two most lateral metatarsals ie the 4th and 5th. Proximally, the talus articulates against the distal ends of the tibia and fibula to form the ankle joint.

There are two more arches commonly attributed to the foot - the lateral longitudinal arch and the transverse arch. The lateral arch is present in varying degree, with the bones of the lateral border as described above sometimes lying flat to the ground on weight-bearing.

The main joints of the foot can be grouped as the ankle joint, the subtalar joint, the midtarsal articulation and the forefoot articulations (Foulston 1987). In the strict anatomical usage of the term a joint, those structures enclosed by a single synovial capsule might typically comprise a single joint. However, in the foot, several articulations function together to form a single structural mechanism.

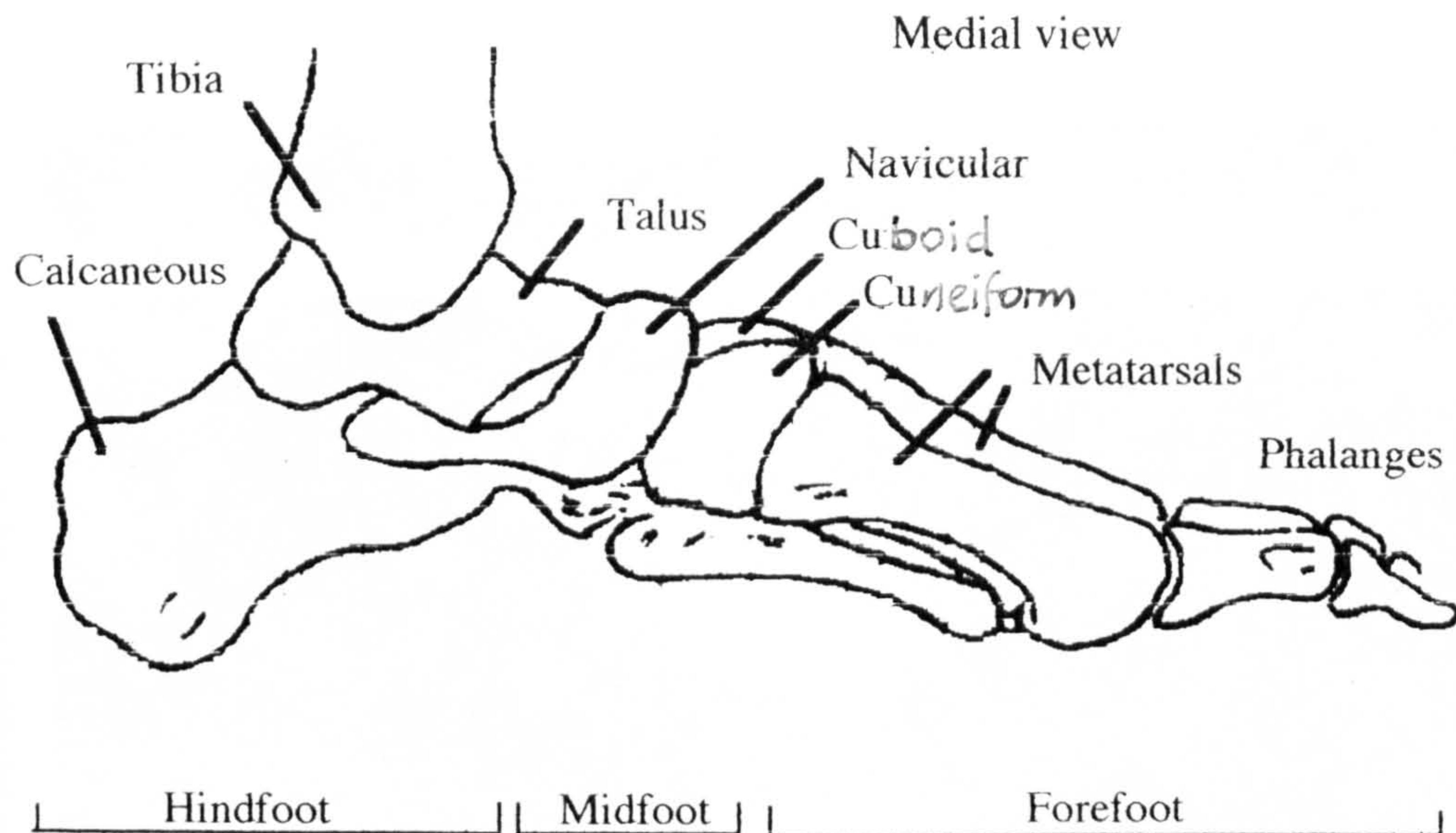


Figure 1.1 Bony anatomy of the foot.

Thus:

the ankle joint comprises the articulations of the talus with the tibia and fibular, which approximate a simple hinge joint with the axis passing through the tips of the medial and lateral malleoli (Inman 1976),

the subtalar joints comprises the articulation of the talus with both the calcaneus and the navicular, which comprises a single axis set at an oblique angle of on average 42° elevation in the sagittal view and 16° inward rotation in the plan view (Inman 1981),

the midtarsal articulation are due to motion at all of the joints onto the cuboid and cuneiforms, which permit a rotation about the long axis of the foot, and

the forefoot articulations at the metatarso-phalangeal joints which act in synchrony to form the 'metatarsal break' during the push-off phase of gait (Inman et al 1981) together with the interphalangeal joints which allow movement in the toes.

The bony anatomy of the foot is surrounded by soft tissues - ligaments, tendons, muscles, fibrofatty material and skin. Ligaments are tough ^{nearly} inextensible fibres which are attached either side of a joint to restrict the motion and provide stability. The motive power of the foot is provided both by extrinsic musculature in the lower limb which

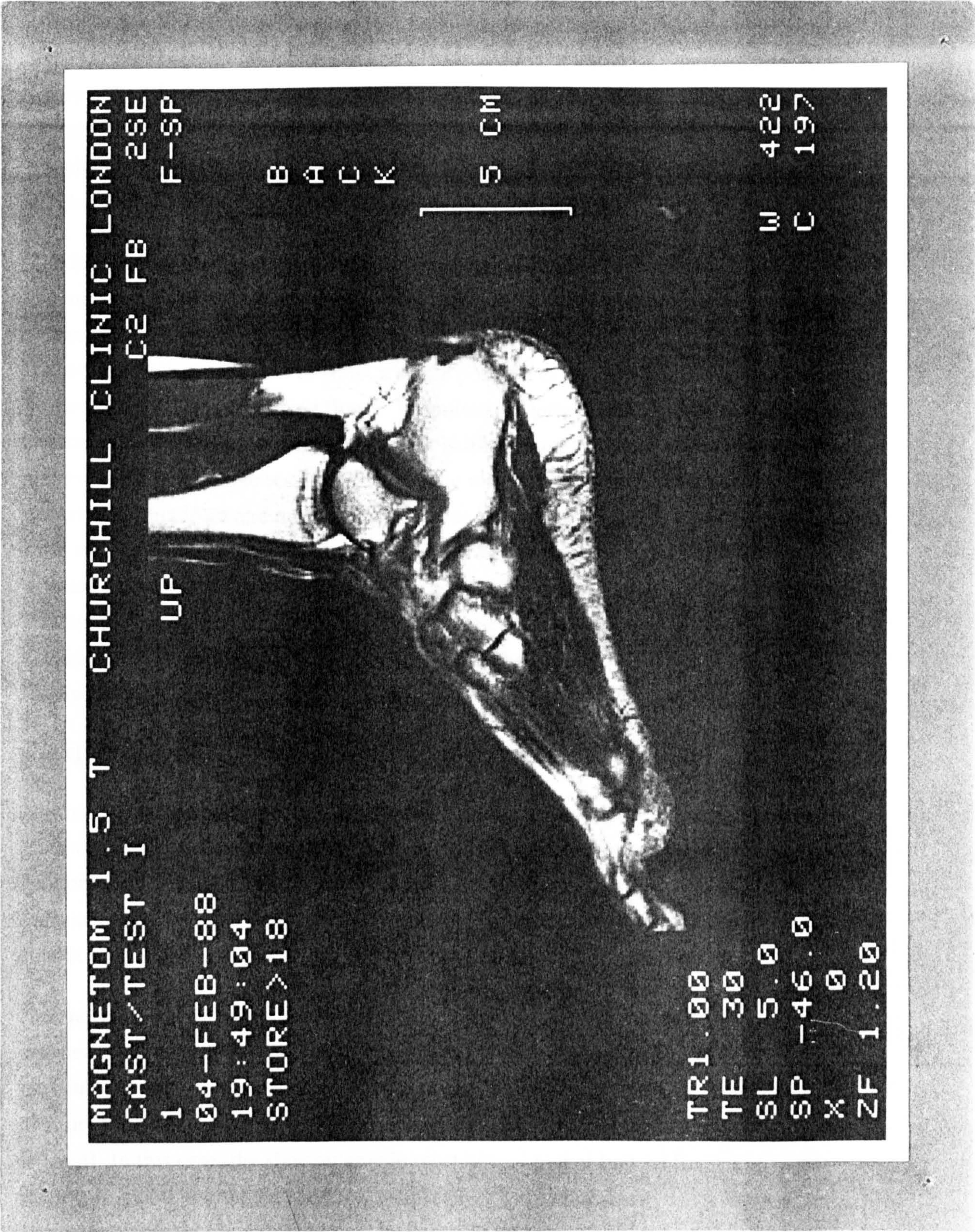


Figure 1.2 Magnetic resonance image of the foot: a longitudinal cross-section midfoot.

inserts onto various bones of the foot via long tendons, or by the intrinsic musculature. The extensive intrinsic musculature under the midfoot is apparent in a longitudinal magnetic resonance image of a mid-slice of a normal (the author's) foot, figure 1.2. Fibrofatty padding under the heel and metatarsal heads cushions the bony prominences during contact with the ground. Finally, the specialised thickened skin on the plantar surface is able to withstand high pressures for long periods without breakdown; the skin on the dorsal surface is much more fragile.

The function of the foot is threefold: support, propulsion and shock absorption (Klenerman, 1991). Through the longitudinal arches, the load from the body's weight is transmitted forward and backwards over a wide base of support. The flexibility of the structure allows the foot to adopt a stable position of support when it comes into contact with uneven or sloping floors. Propulsion is aided by the complex anatomy of the individual bones, which as the hindfoot is lifted from the floor allows for an inversion of the heel: the resulting twist on the midfoot provides a mechanical locking action in the hindfoot and midtarsal joints, thus providing a rigid lever which can be used to propel the body forward at push-off. The longitudinal arches provide the primary mechanism for shock-absorption as the heel strikes the ground in normal gait. The tendons and ligaments of the plantar fascia tie together the ends of the arch and provide a windlass effect, and the arch can flatten thereby extending the plantar fascia to absorb vertical shock loading.

The effect of shoes

Normal shoes have several functional purposes. These are to protect the soft tissues of the foot from external mechanical insult, to cushion the plantar surface and redistribute foot pressure and shearing stresses, and to provide shock absorption, to provide thermal insulation, and perhaps to give support to the bony structure. Shoes affect the functioning of the foot in varying degrees, depending on their construction.

In general, the shod foot is required to make much less adaptation for uneven ground, and hence the ranges of motion encountered at the joints are reduced. This is particularly so if the shoe is of a solid base construction, such as a clog. This feature precludes the flexing across the metatarso-phalangeal break which normally occurs at push-off. In this case, the shoe outer sole must have a rocker bottom feature to enable the whole foot to incline forward (cf. a lancashire or swedish clog, where the toe area is tilted upwards from the line of the metatarsal break) or gait is severely restricted to a flat-foot gait with short steps at a slow speed. Even for normal walking shoes, the stiffer the sole the more the toe-spring (the slight upwards curvature that can be

viewed at the toe end of the sole when the shoe is placed on a flat surface) must be to compensate.

Several changes in the loading of the foot have been demonstrated from pressure distribution measurements. Soames et al (1982) demonstrated that wearing of shoes produced notable effects of load bearing in the metatarsal area. Weightbearing was shifted from the central metatarsals more towards the medial side in shod gait. Also the pressures under the toes increased. The 'impulse' under the heel (viz. the integral of force vs time in this area) is reduced by the wearing of shoes, which correlates with an earlier transfer of the weight towards to forefoot..

Heel height has an obvious effect on foot function. High heeled women's shoes affected the peak pressures under the forefoot in a study by Snow et al, 1992. The study was conducted measuring the pressures between the shoe sole and the floor, and not the pressures at the shoe/foot interface. Walking in a low-heeled shoe compared to barefoot was seen to increase pressure under the lateral metatarsal heads, a finding which was acknowledged as being in direct contrast to that of Soames (1983). The authors of the paper suggested a possible cause of the discrepancy in the design of the shoes, with their high-street fashion shoes cramping the heads and preventing offloading. The forefoot maximum pressures were almost doubled from low to high heeled shoes. The raising of the height of the heel of the shoes from low through medium to high progressively reduced the time from heel strike to the maximum peak pressure under the forefoot, although the support times remained the same. Thus the forefoot is loaded more rapidly and bears load for a longer time with high-heeled shoes. A theoretical analysis by McBride et al (1991) calculated that the metatarsophalangeal joint forces would be doubled by the wearing of high-heeled shoes over barefoot walking, because of the altered geometry. An experimental study of women's high-heeled shoes supports this theory, since the metatarsal pressures were approximately doubled from barefoot to a 8 cm heel (Snow et al 1992).

Medical Conditions and Design Requirements

The need for orthopaedic footwear can arise as a result of a systemic disorder which has foot complications, such as diabetes and rheumatoid arthritis. It may also arise as the result of congenital or acquired orthopaedic deformity; hallux valgus is the major presentation in this group.

Diabetes

Foot complications occur in a small but significant number of patients with diabetes mellitus. It has been estimated that 12% of all hospital diabetic admissions result from foot problems (Connor, 1987). The problems are typically described as being either vascular or neuropathic in origin. Vascular problems result from the blocking of the arteries, whereas neuropathic problems are the result of the altered body chemistry which affects in particular the small nerves in the peripheral structures.

The vascular foot typically has an insufficient blood supply with poor pulses and feels cold. Because of insufficient oxygenation, the skin is fragile and ulceration is frequently seen on the dorsal surface where shoes rub. The foot may be hypersensitive. In contrast the neuropathic foot is abnormally warm and dry. It often develops claw-toes due to imbalance in the intrinsic muscles, tends to form excessive callus and to ulcerate on the plantar surface, and usually has impaired sensation.

It has been demonstrated that diabetic patients with a history of neuropathic plantar ulceration have abnormally high pressures under the foot in walking (Stokes et al 1974; Ctercteko et al 1981; Boulton et al 1983). Peaks of pressure occur most frequently under the metatarsal heads. This is due to anterior migration of the fibro-fatty pad associated with clawing of the toes, which leaves the metatarsal heads uncushioned. High plantar pressure correlate well with the sites of ulceration. Reduction of the pressure peaks can be achieved by the provision of special shoes with deep inserts (Cavanagh et al, 1987) which form an important part of an effective management programme for the neuropathic foot.

The specification of shoes for diabetic neuropathy includes provision of

- extra depth shoes to accommodate cushioning inserts for reduction of pressure peaks
- extra depth in the toe box and soft uppers to prevent rubbing on claw toes
- a good fit in the hindfoot and secure fastening to prevent any sliding action which could result in plantar shear and pressures on the distal tip of the toes

and in more severe cases

- moulded inserts to distribute the load into the midfoot
- rocker bottom outsoles to reduce the loading under the metatarsal heads (Geary & Klenerman 1986).

The problems of the vascular foot are quite different. The primary action must be to restore the circulation via surgery, without which the foot may become unviable. The

main requirement of any footwear provided for these patients is to prevent excessive pressure and rubbing of the shoe on the dorsal surface of the foot.

For completeness it is worth mentioning Hanssen's disease, known previously as leprosy, whose incidence is now waning with the advent of new drugs. It does however still occur and leave some residual problems with the extremities. The disease attacks the nervous system, and the problems are close to those of diabetic neuropathy, those of the insensate foot; the requirements for shoes are similar. Footcare developments at the world-famous Hanssen's Disease Centre in Carville Louisiana inspired by its previous director, Dr Paul Brand, have contributed greatly to designs of footwear for the insensate foot.

Rheumatoid arthritis

A very high percentage of adult patients with rheumatoid arthritis experience problems with their feet, up to 90% (Vainio, 1975). These are a result of the destruction of the joint surfaces and disturbance of the tendons and ligaments which stabilise the joints, so that the complex structure of the foot becomes unstable. Foot deformity may follow, of which the five most common features are hallux valgus, pronation of the foot, depression of the metatarsal heads, claw toes, tendocalcaneal bursitis *i.e.* spur formation (Dimonte & Light, 1982). The rheumatoid foot becomes hypersensitive and painful.

Much of the resulting pain is related as much to aspects of the deformity as to the underlying tenderness of the inflamed tissues. Patients typically describe a sensation of 'walking on pebbles' under the ball of the foot, because the fatty pad which normally acts as cushioning between the metatarsal heads and the skin has been displaced forward by the clawed toes. Also very common are problems in the hindfoot, where the weakening of the subtalar joint allows the heel to collapse into inversion as part of the process of inversion. This puts the entire hind and midfoot out of alignment, poses a strain on all of the interconnecting tissues, and prevents the foot from functioning normally. Other complications include hallux valgus (angulation of the great toe towards the second toe), bunions on the outside border of the first metatarsal head, collapse of the longitudinal arch of the midfoot, tenderness at the insertion of the Achilles tendon on the heel bone, and occasionally bony spurs on the heel.

The functioning of the foot in gait cannot be divorced from that of the rest of the body. Weakness in particular in the calf muscles, restricted ranges of motion in the ankle, and involvement of the joints higher up the leg (Locke et al, 1984) all contribute to abnormal gait patterns which can further exacerbate the foot problems. In rheumatoid gait the foot is abnormally placed flat onto the ground and lifted in the same way

(Soames et al, 1982 & 1985). There are several reasons for this. It may be a protective mechanism to minimise movement (and pain) in the joints of the foot and ankle. Alternatively it may also be a consequence of the misalignment of the joints which is known to prevent normal functioning of the foot as a lever at push-off: the weaknesses and involvement of the leg are also probably contributory. Both pain and dysfunction can lead to a progressive reduction of mobility, which may be severe. The first line of attack for management of the rheumatoid foot is to provide suitable footwear. The objectives of the footwear must be to reduce pain, to prevent deformity and to assist in walking.

The primary requirements can be summarised as provision of

- cushioning under the ball of the foot
- adequate forefoot width to prevent compression of joints
- accommodation of any fixed deformities eg extra-depth in the toe-box to prevent rubbing on the dorsum of clawed toes
- support and maintenance of flexible joints in hindfoot and midfoot
- in extreme cases, immobilisation of the joints
- reduction of shock loading
- lightweight construction in deference to sensitivity
- ease of donning and fastening

The last point recognises that the wearer may not find it easy to reach the shoes and put them on due to involvement of proximal joints of the body, nor to do up the fastening if they can reach due to hand complications.

Orthopaedic Conditions

The most common orthopaedic condition occurring is that of hallux valgus, a deformity where the great toe deflects towards the midline of the foot. In extreme cases, the hallux will cross over the adjacent toes and may even cause adjacent metatarsophalangeal joints to sublux. Hallux valgus, most common in women, has hereditary tendencies, although it has been suggested that there is a link between the wearing of tight shoes and the hallux deformity (Sim-Fook & Hodgson 1958). Hughes (1991) examines the evidence, and concludes that this is not yet scientifically proven. The orthopaedic presentation and surgery for this condition is well-documented in Edgar & Klenerman, 1991, together with the condition of hallux rigidus , a painful limitation of dorsiflexion motion at the 1st metatarsophalangeal joint which has a similar treatment.

Treatment is primarily surgical. Nevertheless it is recommended that the foot with hallux valgus should be fitted with a shoe which is made on a last with a straight medial border, so that no medial pressure can be exerted to push the hallux further out of line at the metatarsophalangeal joint.

Other less frequent deformities due to congenital pes planus (flat-feet), congenital vertical talus, metatarsus adductus, and talipes equinovarus (clubfoot) also usually require surgery as described by Fixsen, 1991. Footwear may then be needed to accommodate fixed deformities resulting from fusion of impaired joints or misalignments which cannot be totally corrected.

There are many instances of milder hindfoot instabilities, primarily pronation at the subtalar joint, and also of pronated forefeet. These conditions can be treated with posted (ie. wedged) shoe inserts to realign the foot.

Patient Population

Demographic factors

Population statistics for disabled persons in Great Britain were collected in a major government survey carried out in 1985/6 by the Office of Population Censuses and Surveys (OPCS,1988). These showed disability rates of 9.2% for males and 12.6 % for females , with an population of 6.2 million disabled adults out of the total population of 56.6 million .

Prevalence of disability is strongly correlated with ageing. OPCS data on population shows an increasing trend above the age of 50 and marked increases above 70. Additionally, the figures for life expectancy at birth for the total population of England and Wales show a rising increase, with average life expectancy increasing in 1982-84 compared to 1952-54 from 67.3 to 71.6 years (males) and 72.7 to 77.6 (females). Reduction of causes of premature death which result in these longer life expectancies allow the normal ageing to occur with its associated degenerative processes. Although improvements in medicine can moderate or even obviate the effects of disabilities caused by disease in a number of cases, the prevalence of disability is generally expected to increase as the population becomes increasingly aged.

Locomotor problems are the most common type of disability. A rate of 99 per thousand , or over 4 million people, have this type of disability. In those disabled adults living at home, disorders of the musculo-skeletal system are most common, with three-quarters of these ^{having} arthritic conditions. A report from the Arthritis &

Rheumatism Council (Tennant & Badley ,1990) provides more detailed information on the nature and extent of disability with self-reported rheumatic disease. Based on the survey of the Calderdale district in Yorkshire, a prevalence rate of 79.1 per thousand was found, slightly higher than the OPCS average figure even allowing for the regional variations.

Since arthritic patients represent one of the major groups of consumers of the footwear service, it can be expected that the demands for this service will increase in line with the demographic trends, failing medical breakthroughs in prevention and cure of arthritic diseases.

Medical factors

Improved medical care is paradoxically another factor which is also leading to increased needs for footcare in the diabetic population. Such advances prolong life but allow for the emergence of peripheral neuropathy and vascular problems in a sector of these patients. Their greater life expectancy extends the period of care needed and the consequent demand on the orthopaedic footwear service. This is part of the general trend for increased life-span mentioned earlier.

1.3 TRADITIONAL ORTHOPAEDIC FOOTWEAR DESIGN

Bespoke Shoes

A bespoke orthopaedic shoe is one which is individually made for the patient. For fairly normal shaped or moderately deformed feet, the process begins with measurement of the feet individually. British Standard 5943:1980 'A Method for Measuring and Casting for Orthopaedic Footwear' describes the basic process. This standard specifies the basic methods for the taking and recording of all details of the feet necessary for the manufacture of orthopaedic footwear. BSI standards are covered by copyright, and therefore a brief description only is given here. The Standard describes

- | | |
|---------------------------------|--|
| (a) initial information: | this describes the clinical details to be taken, the measuring equipment & charts to be used. |
| (b) allowances on measurements: | last allowances may specified, ie. the differences in dimensions/shape of the last over that of the foot. |
| (c) outline diagram of foot: | this is the plan view of the foot, drawn around the foot with patient seated, the shin vertical and the foot weighted, using a 7 mm pencil held vertically |
| (d) girth measures: | these are circumferential measures taken at the joint, waist, instep, long & short heel, using a tape measure, and the positions of the tape are indicated on the outline: the girth around the malleoli is also required for boots. |
| (e) foot length measure: | this is taken from the heel to the toes, using a simple caliper size stick laid along the medial aspect of the foot. |
| (f) height measures: | these are taken to indicate dorsal prominences with the respective position marked on the outline, and the malleoli heights. |
| (g) cast taking procedures: | this describes the method of making whole foot and plantar impressions, if these are deemed necessary |

- (h) specification of construction: details specified can include basic types of footwear construction, stiffeners, inlays, wedges etc.

A typical measuring chart is suggested. The majority of UK manufacturers use the suggestion as a basis for their own company's form. Figure 1.3 shows an example of the outline, girth, foot length and girth measurements which should be recorded for each foot on the chart.

A shoe last must then be made for each foot separately. This is the former over which the shoe leather will be pulled into shape. The last can be made of wood, but is now more often a hard thermosetting plastic. It has a hinged construction so that it can easily be removed from the finished shoe, figure 1.4. In the UK, the basis for the last is a fashion last selected from a batch of cast-offs from the volume trade.

The last-maker selects a 'basis last'^{*} which meets his approximate needs, and then adjusts the shape by the addition of plastic or leather patches to match the corresponding measures, making insert allowance on the last, figure 1.5. There are no hard and fast guidelines for this process.

When a suitable last shape has been arrived at, the pattern-maker begins his part of the process. There are several different procedures for pattern generation, which all result in a set of paper patterns for the upper parts. Leather and stiffeners are then cut to these patterns, in the process known in the volume trade as clicking. The upper is then closed, by sewing together all the flat parts, figure 1.6

The closed upper is now ready to be pulled over the top surface of the last, a process which forms the flat leather into its three-dimensional form. This can be done as a hand process, but the larger companies now use automated machinery. Typically the edges are tacked down onto the bottom surface of last, figure 1.7. A sole is fabricated out of leather or otherwise, grinding the edges to conform to the sole of the last. The sole might be welted or stuck on. Heels are then attached. Finally the shoe last is removed and the insole positioned.

Most shoes are sent for trial fitting. The shoes are initially only 'rough finished' as specified in BS5943, in that the upper is only temporarily tacked down, a temporary sole attached and the insole positioned, so that the shoes can be sent for a clinical fitting. On return, the last and uppers might be adjusted in response to the fitter's comments. Then the final soling is done.

* basis last - ie. a last which is used as a basis for customisation: this may be a stock orthopaedic last, a redundant last from the fashion trade, or even the last of another customer which is no longer needed.

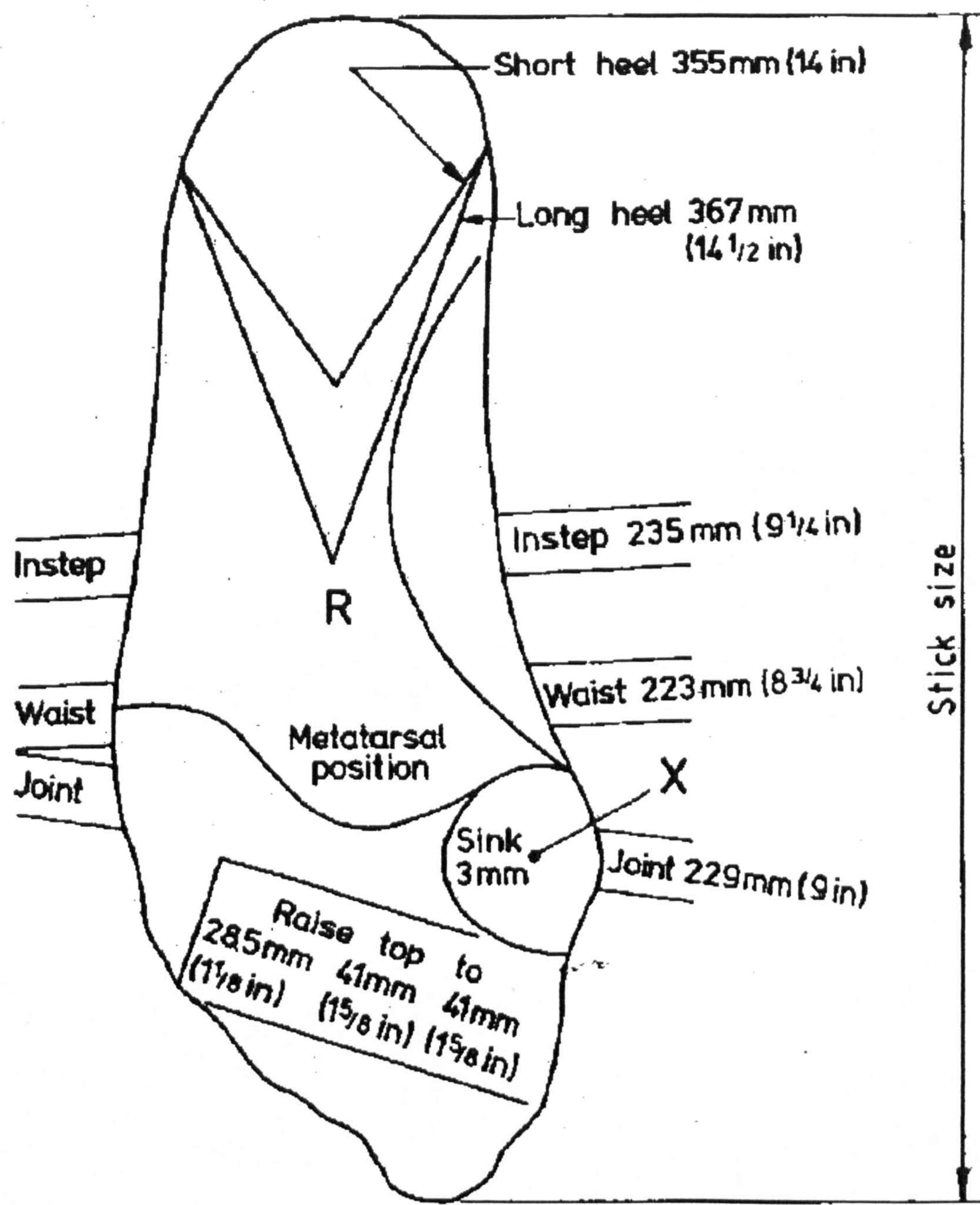


Figure 1.3 Set of foot measurements taken according to BS 5943

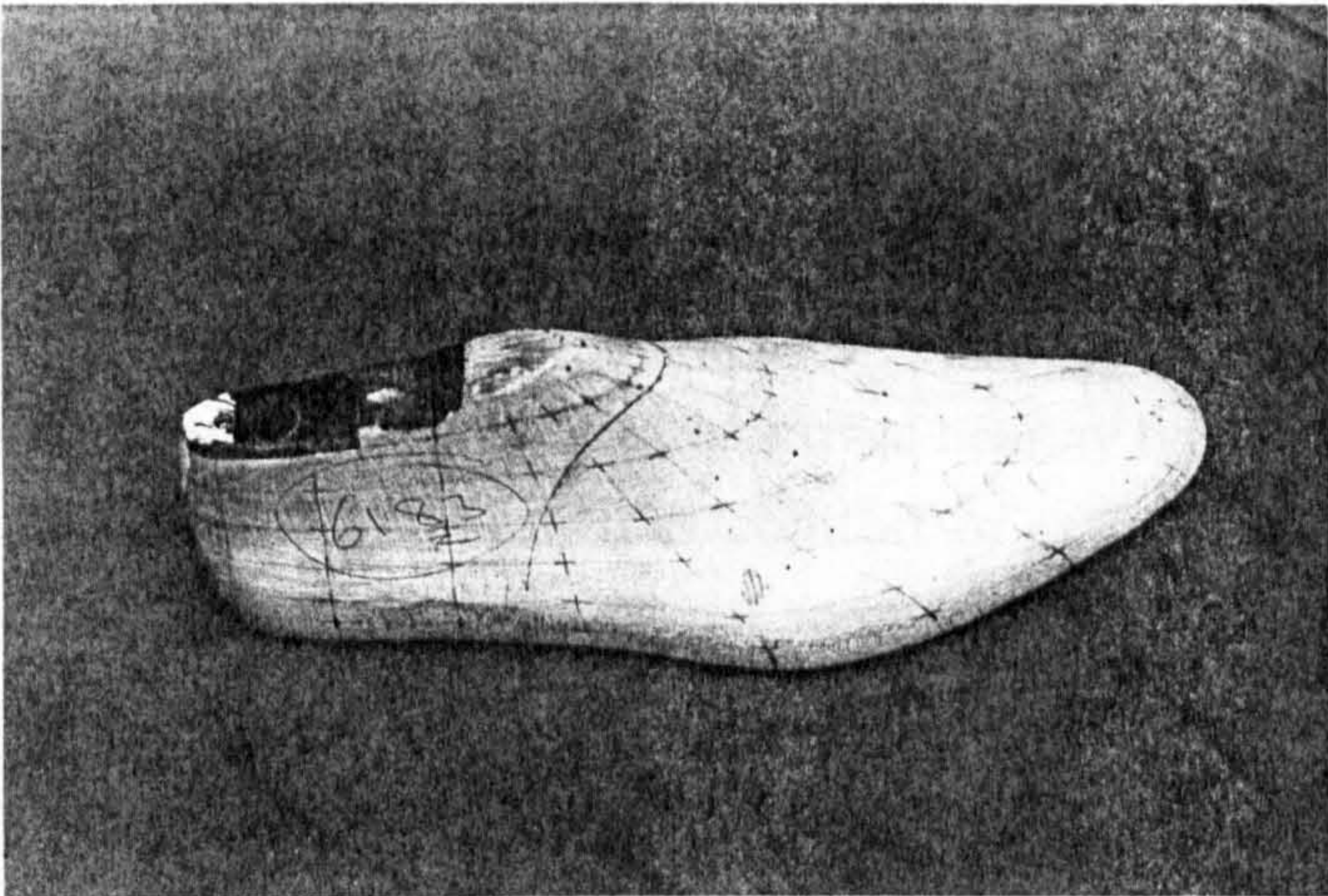


FIGURE 1.4 A SHOE LAST

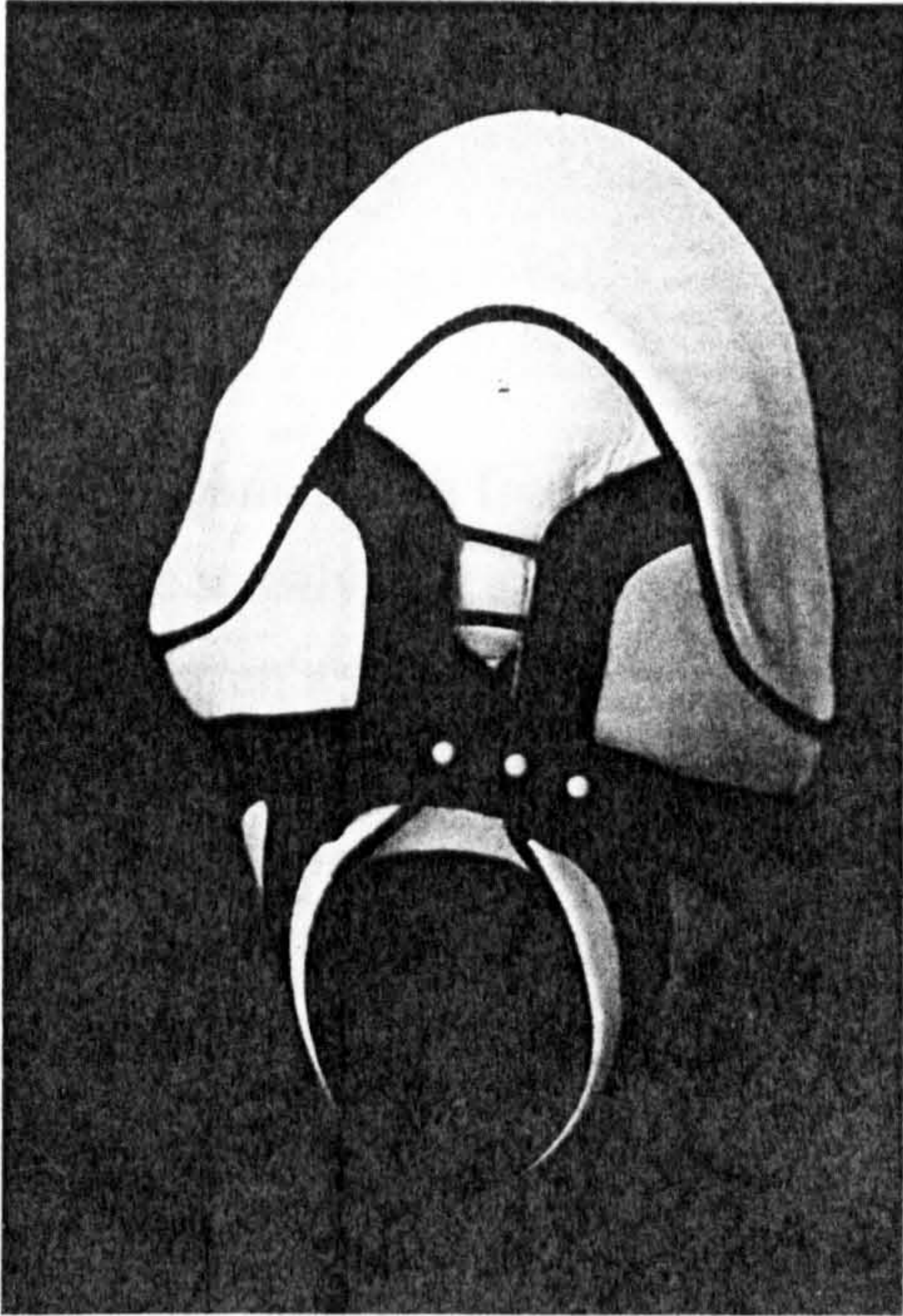


FIGURE 1.6 A CLOSED SHOE UPPER

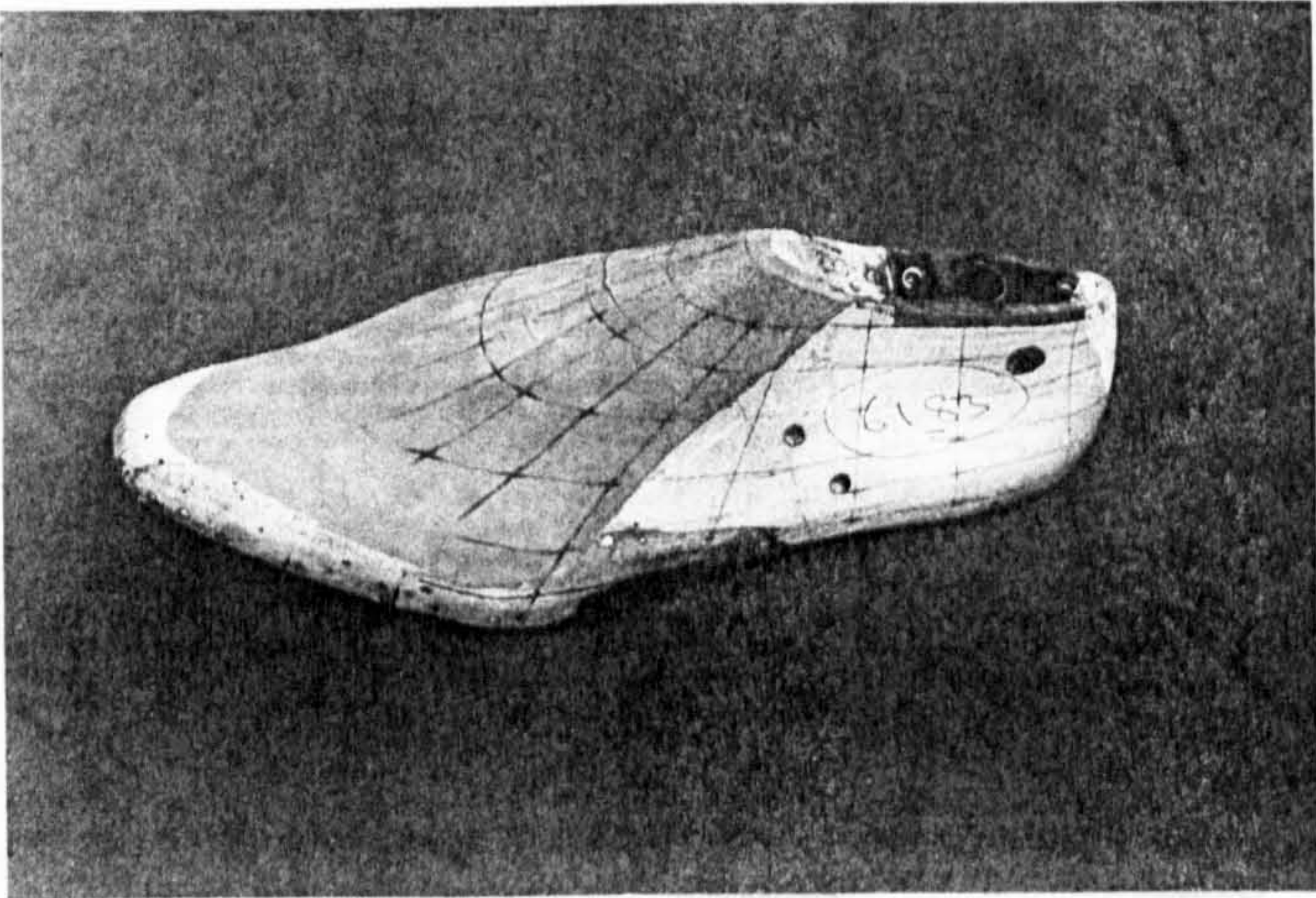


FIGURE 1.5 ADJUSTED SHOE LAST

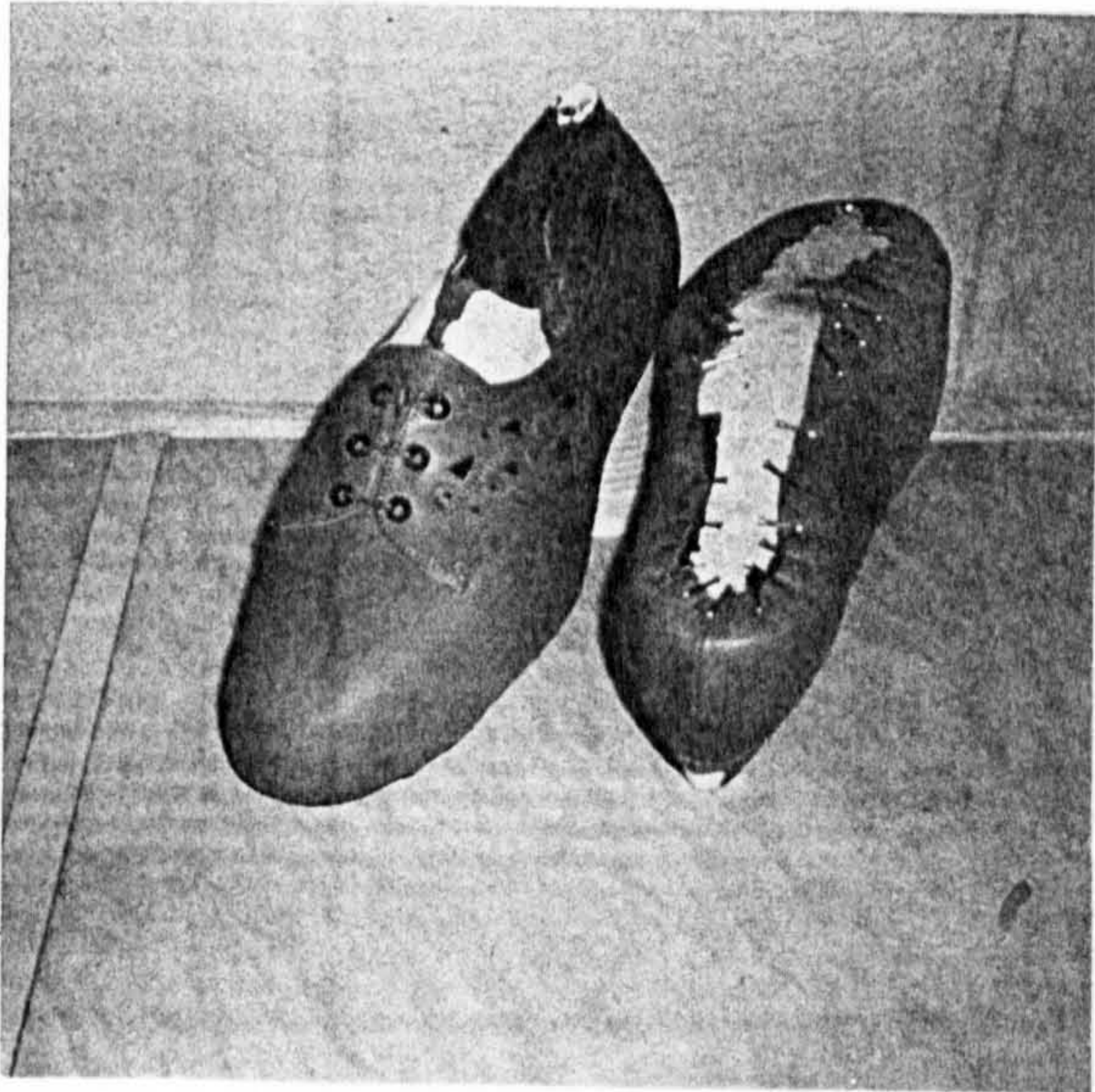


FIGURE 1.7 SHOE UPPER TACKED TO THE LAST

Variants on this process occur where the feet are grossly deformed, and sometimes where a moulded insert is specified for pressure redistribution purposes on a normally shaped foot. In these cases, the feet are cast in the clinic to provide a positive of the required shape. The positives, either made of plaster or often Pedalin hard-setting foam (supplier Otto Bock), are themselves adjusted in shape to build in last features, eg. the toe is built out, the instep is raised and the heel clipped in. An insert is built up to mate with the bottom surface of the positive, and shaped so that the lower surface becomes in effect the sole of the last. The shoes are then fabricated over the combination of positive and insert.

Stock Shoes

Ranges of stock orthopaedic shoes are offered by various companies both from the UK and abroad. The distinguishing features of these shoes are mostly that the last is of a sensible foot-like shape with extra depth in the toe box, and often a full-length extra depth is allowed to leave room for a special thick insert, flat or custom-made. The shoe construction should be of an approved healthy type, and the materials a good leather. The shoes are also known as 'comfort' or extra-depth'. In fact, the name 'stock' can be misleading: the shoes are not necessarily in stock at the manufacturers or the fitter's home company. Very often the shoes are ordered from a catalogue and made-to-order over a stock last, and then may take several weeks to be delivered.

The use of stock shoes ordered from a catalogue is limited by the difficulty in obtaining the correct size first time. Standard volume sizing of shoes by length and width is only appropriate to allow an assistant in a shoe shop to select a first trial pair. It cannot guarantee a fit. Shoes of the same nominal size made over different lasts will have different fit characteristics. However the use of stock shoes, often with very deep custom inserts which can accommodate size problems, is gaining favour.

1.4 SERVICE ORGANISATION

Regulation of Supply to the NHS

Under DHSS rules appertaining at the start of this study in 1987, the supply of footwear to the NHS is regulated centrally through one Health Authority. The documentation is contained in Booklet MHM 50, Provision of Medical and Surgical Appliances, issued by North West Thames Regional Health Authority. This booklet describes the process of prescription, the basic types of footwear that can be prescribed, the materials that must be used and gives a schedule of approved additional features that can be specified. All manufacturing procedures and materials are required to conform to standards for which SATRA§ are the testing authority. Each company which wishes to supply the NHS is required to tender annually for a contract with the central authority for the specified services which they wish to provide. The contract covers standards of manufacture and delivery, and prices. The company is then free to bid to provide those services with the individual clinic or hospital.

In 1991, the central responsibility for footwear passed to the Centre of Responsibility for Rehabilitation Products, Medical Devices Directorate, at Sheffield. This organisation undertook an analysis of the problems of the supply system (The Orthotic Service, Department of Health, 1991), which identified that the regulation method had produced difficulties in innovation in supply. This has resulted in significant changes in the regulation, particularly in the negotiation of contracts.

The following sections cover the detailed description of the supply route which has resulted from the central regulation.

Prescription of Orthopaedic Footwear

Under DHSS rules appertaining in 1987, the right to prescribe surgical footwear lies solely with hospital consultants. Furthermore the obligation to ensure that the appliance is satisfactory also resides only with consultants with the exception of only a minority of pre-notified cases where direct delivery to the patient is ordered:

12. The hospital may order and provide an appliance for a patient only when a patient has been examined and the appliance prescribed by or under the

§ Shoe and Allied Trades Research Association, SATRA House Kettering.

direction of a consultant, either at a hospital or clinic, or on the occasion of a domiciliary visit.

13. It is for the consultant dealing with the patient to prescribe whatever appliance is considered necessary for the patient's condition.

50. Appliances are not normally supplied direct to patients by contractors but are sent to the hospital. The consultant is responsible for ensuring that each completed appliance conforms to the prescription and is satisfactory in manufacture, fit and function when worn by the patient.

(Part 1, Booklet MHM 50, Provision of Medical and Surgical Appliances: recent changes have not substantially altered these provisions)

Orthopaedic surgeons, diabetologists and rheumatology & rehabilitation consultants are the main groups of consultants involved in footwear prescription. Other consultants may also be involved from time to time usually to a much lesser degree.

Members of the chiropody profession may prescribe special footwear adaptations and shoe inserts in the community. The General Practitioner has a very restricted right to prescribe certain shoe inserts.

The entitlement to bespoke orthopaedic shoes is normally one pair per annum; this can be extended to two pairs if justified by activity or life-style eg. work shoes and casuals required. The consultant can prescribe only for 'orthopaedic' conditions, which is interpreted differently at different centres, and only if the foot cannot be fitted in standard shoes even if adapted. The consultant can alternatively choose to supply extra-depth stock orthopaedic if he thinks these are adequate: in some recent publicised cases, patients have been advised to buy these stock shoes themselves, and then moulded inserts only are provided by the NHS.

The types of orthopaedic footwear that can be prescribed are

- bespoke shoes or boots of basic styles and with specified extra features
(raises, wedges, etc outlined in MHM 50)
- orthopaedic stock shoes (which are regulated only by very broad requirements)

Adaptations to the patients own footwear, or special shoe inserts, can also be prescribed.

Involvement of NHS Clinical Staff

Footwear prescription and responsibility for checking is the preserve of consultant medics. Other clinical staff employed by the NHS and involved in footwear delivery include senior registrars, chiropodists, occupational therapists, physiotherapists, nurses and, to a limited extent, GPs. Recently a few hospitals in England and rather more centres in Scotland have employed a hospital orthotist who plays a major role in footwear supply.

The Supply Route

The supply route for bespoke footwear is through a commercial contractor. An order initiated by the consultant's prescription is accepted by an orthotist working in the clinic as a representative of a contractor appointed to the particular hospital. The bespoke footwear is produced off-site for subsequent delivery at a later clinic. The NHS contract requires that the footwear is available for fitting normally 6 weeks after the measurements are taken. Modifications and shoe inserts may be made on-site by NHS staff or the contractor.

Communication routes from the consultant issuing the prescription to the contractor's orthotist accepting the order varies. Probably the most typical route is for the consultant to communicate his requirements directly to the orthotist, preferably in the clinic with the patient present. However there are known to be many variations on this pattern.

Also the degree of detail specified on the prescription varies widely, with only some writing a technical specification. Sometimes the consultant delegates to a medical colleague with special interest in footwear, or may pass the prescription to the appliance officer to negotiate the details with the fitter. Various other intermediary clinical staff are also said to be delegated to work out the details of the prescription, often with reference to particular problems - the physiotherapist for neurologically-impaired children, the chiropodist for diabetic patients etc.. The hospital orthotist, where employed, may often be the person of choice to act as intermediary.

Within the hospital, the Appliance Officer is employed to deal with the ordering and checking. This includes obtaining details of the footwear, taking advice from the fitter if it is the consultant's practice to leave detailed specification to the contractor, and interpreting the specification into appropriate codes for the scheduled item charges. The Appliance Officer then progresses the order, and checks at delivery that the

footwear conforms with the scheduled items ordered. The item is also checked for manufacturing defects, such as impaired finish.

Charges

There is at present no charge made to the patient for footwear supplied on prescription. A schedule of prices for certain items is agreed between the contractor and the central purchasing authority: this is done by tender and can be different for each contractor within certain limits. Conditions appertaining at the start of the study required the contract prices to be upheld in the supply to any NHS facility, although some local negotiations have been occurring recently. Until 1991, the contract price included both the product cost and the cost of service (measuring, fitting etc). It is now possible to separate out these two factors, with a price negotiated for attendance of the fitter at the clinic divorced from the charge for the products he might supply. The fitting fee can be arranged per item, or as a session fee for attendance of the orthotist at a specified clinic.

Audit of Supply Costs

Centrally, no continuous record is kept on provision of footwear, either nationally or regionally. The latest figures found were contained in an internal DHSS report and related to supply in England and Wales during 1978; these show the total number of items ordered and the value as a percentage of total for all surgical appliances by broad categories of

- A. Surgical Footwear and Additions
460,490 items, 29% of total cost
- B. Adaptations to Footwear
675,563 items, 10% of total cost
- C. Footwear repairs
235,857 items, 2% of total cost

In some cases individual clinics or hospitals are able to supply some data collected by their own initiatives. The Dundee District of the Tayside Health Board keep computerised records of their orthotic supply. For 1979/80, attention is drawn to the high number of repairs and modifications which were carried out to footwear, representing 26% of all commercial orders for orthoses by cost (Murdoch et al 1984). A further 26% of orders were for shoe inserts (insoles, heel cups, cradles), a large proportion of which were for replacement or duplicate devices. In a further internal

report for 1984 the expenditure for each item with a percentage of cost of all limb orthoses and corsets was:

A. Surgical Footwear	£20,051	39% of cost
B. Shoe adaptation	£3,511	7% of cost
C. Repairs of SFW/Shoes	£3,683	7% of cost
D. Non-customised Shoes	£3,310	6% of cost
E. Shoe inserts	£5,735	14% of cost

A report commissioned by the Southampton and South West Hampshire Health Authority (1986) reviews the orthoses and special footwear services. This gives figures for expenditure in 1985/6 at the Southampton General Hospital :

A. Surgical Footwear	£146,594
B. Adaptation to footwear	£29,602
C. Repairs to footwear	£17,442

These costs represent 51.5% of the total expenditure on patients' appliances, which in their report include limb prostheses, supports, wigs and walking aids but exclude dental and optical appliances.

Research and Development

Research and development in rehabilitation engineering has in the past received central funding from the then Department of Health and Social Security. This funded the Biomechanical Research and Development Unit at Roehampton, which latterly became in 1980 the Bioengineering Centre, UCL, until its closure in 1990. Other funding was put out as project grants to both research centres and for industrially-based developments. Central funding has been diminished for such work over the past five years in a projected move to regional funding through the NHS. At present NHS funding for all Research and Development work is 0.8% of its annual turnover, with the policy that this should move to 1.5% over the next four years (Peckham, 1991).

Because of our supply system, industry has previously had little financial commitment to R&D. The UK industry has only one main domestic customer - the government in the form of the NHS. Private consumers represent a very small market although this is the subjective opinion from informed sources since figures are not made available. In turn, the NHS has restricted its suppliers by a process of national tendering for many items. Within this system, it was previously understood that central grants were available for development work from the DHSS, as previously mentioned. The basis for this tendering has been altered substantially following a reorganisation with

formation of the Centre of Responsibility for Rehabilitation Products at Sheffield . In personal correspondence(May 1991) with the Director of the Centre over the sources of R&D funds in future, he states that " we would expect companies to cover any R & D costs through their normal turnover....I would personally reckon that an innovative company ought to be spending anything up to 8% of turnover on R & D..". Other changes in tendering have opened the market to competition from abroad, and in other related areas such as prosthetic limbs there has been a notable influx of overseas companies. UK companies have also begun to be more export conscious, with for example, one of the major prosthetics and orthotics companies (Steepers Orthopaedic Ltd) gaining contracts for supply of prosthetics to the USSR and to the middle east (source of information: discussions with the Director). Government policy is to increase the competitive scope, and industry will correspondingly need to increase its R&D commitment to compete.

A document issued in January 1991 by the National Centre of Responsibility, Orthotics: A strategy for Procurement comments under the heading of Investment and Innovation -

" Although CAD/CAM facilities can be appropriate to the industry, suppliers are either unwilling or unable to invest. Research into these techniques is now being funded through EEC grants and being undertaken by university/NHS facilities. Meanwhile the industry continues with outdated machinery and techniques."

This situation is already changing. In footwear, the largest supplier (Remploy) has invested late in 1991 in a 2D system for pattern cutting. Another large company (Camp Ltd) is trialling CAD last design and yet another is expected to install a 3D CAD system in the near future.

1.5 THE CONSUMERS VIEW OF NHS ORTHOPAEDIC FOOTWEAR

Patient Satisfaction

Data is available from previous reports on patient satisfaction with footwear, although this is subjective and can be influenced by the selection and data acquisition process. Nevertheless this is important in assessing the patients' priorities and problems, in addition to the functional priorities of the prescriber, particularly so since the patient can often chose not to wear the shoes if they do not like them. Lack of patient compliance in this respect can lead to a waste of NHS funds at the least, and at the worst, a serious deterioration in the condition of the patient's feet. Conversely, some — patients are forced to wear the provided footwear even when they express dissatisfaction, for a variety of reasons which include the inability to obtain any alternative and pressure from the clinical team.

Factors which affect the results of surveys should be borne in mind when assessing the significance. When the questions are asked is important. Does the response represent the initial feeling of the patient faced with wearing 'orthopaedic shoes' for the first time, or the longer term outcome? Who asks the questions is also vital, since it is not uncommon for patients to attend clinics in their otherwise obviously unused footwear in order to please the clinic team, and likewise to make positive comments so as not to appear critical of those trying to help them. Others fear that a negative response might prejudice future supply. Patient selection can obviously bias the outcome. Most of the surveys have attempted to deal with these problems in their reports.

In a report carried out in 1976 by the Research Institute for Consumer Affairs on behalf of the National Fund for Research into Crippling Diseases (Jay & Dunne,1976), 100 patients with surgical footwear selected by the Consultants at a variety of major London Hospitals were interviewed by the researchers and a questionnaire completed which detailed patient's life-style, all aspects of provision and wearing of NHS , satisfaction and problems with this footwear. Selection criteria specified roughly equal numbers of women and men who had been supplied with appliances within the previous 6 months to 2 years, representing all the suppliers used, and excluded those with severely deformed feet or those requiring raises of two

or more inches. The Consultant or Appliance Officer filled out clinical details and technical description of the footwear. . Dissatisfaction arose from

inadequate provision : 34 out of 100 have only one pair, with only 'a small minority' feeling that this was satisfactory,

poor styling : 30% of women and 6% of men were dissatisfied, with the reasons primarily that the shoes were not 'sufficiently feminine/modern/elegant or that they were too clumsy/heavy',

poor comfort : 50% stated that the shoes were very comfortable, a further 20% fairly comfortable but 25% had given up wearing the shoes or found them uncomfortable,

difficult to put on: about half the patients found the shoes difficult to put on - all but one pair for these 50 patients were lace-ups and there was in nearly all cases a medical condition which caused difficulty in doing up the fastenings or bending down to reach the shoe,

lack of repairs: approximately 35% in a poor state of repair for various reasons related to . misunderstanding the process of getting this done.

In another report by the Office of Population Census and Survey (1979) on a study carried out in England and Wales, 18% of patients were dissatisfied with their footwear, with the four main problems given as comfort, style, durability and delivery. The recommendations of working parties such as that convened by RADAR (Royal Association for Disability and Rehabilitation) on the supply of orthotic appliances (Guthrie, 1983) and the Scottish Home and Health Department (SHHD, 1980) following the publication of these adverse consumer surveys were intended to improve the provision by suggesting a number of measures relating to the clinical procedures, manufacturing processes, supply entitlement and training of those involved. However there were few immediate changes in practice with the exception of isolated action at a few centres such as in the Dundee district, where a hospital orthotist was appointed and an active programme pursued for the development of the orthotic service(Murdoch et al, 1984) via innovative fabrication facilities and team assessments at a new orthotic facility in the Dundee Royal Infirmary. . Two further surveys at Southampton and Nottingham would suggest that the dissatisfaction and rejection rates are still similar at other major hospitals .

A questionnaire assessment of patient satisfaction was undertaken by Fisher and McLellan (1989) at the Southampton General Hospital. Dissatisfaction with made-to-

measure footwear was expressed by 39 out of 180 (21.7%) patients. Include in these numbers were 15 who were also dissatisfied with the delays in provision. The main criticisms were that the footwear did not fit (14), were too heavy or clumsy (16), and were cosmetically unacceptable(10). To a lesser degree, complaints were received that the footwear had caused lesions, increased discomfort and reduced walking ability.

A group of researchers at Nottingham (Costigan et al, 1989) have reviewed 82 patients given shoes two to three years previously at the General Hospital Nottingham, of whom 59 were women and 23 were men. This survey represents the longer term outcome of the group selected at the time of delivery. The survey was undertaken by a domiciliary interview by two 'trained female interviewers'. The results state that 8 patients were given comfort shoes, and 74 had bespoke shoes: 49 wearers of bespoke shoes and all wearers of comfort shoes 'were so satisfied with their shoes that they would want a repeat prescription'; 50 wearers of bespoke shoes thought that their shoes were of benefit. This data indicates that 24 out of 74 wearers of bespoke shoes (32%) felt that their shoes were not of sufficient benefit to warrant a repeat prescription. Given that subject selection excluded those where an operation had negated the need for surgical footwear, this result can be interpreted in two ways which cannot be determined from the stated results. Either the initial prescription was unnecessary, or the provision was unsatisfactory. The survey also indicates that 14 patients no longer wore their shoes: however the reasons for this are not stated. Of the 82 original patients, 66 continued wearing the footwear but ' even patients who still wore their surgical shoes were often dissatisfied, the reasons being the inability to fasten the shoes themselves .. and the appearance of the shoes'.

The dissimilarity in the conduct of these various surveys, and suspected regional variations, do not permit any analysis of the trends but show a continuing level of dissatisfaction with footwear provision of about 25% ($\pm 10\%$, say) despite the recommendations of both RADAR and the SHHD. Reasons for dissatisfaction include cosmesis, difficulty with donning, fit , functional outcome, repair facilities and delivery times. Some of the causes were in poor prescription, others in poor specification and manufacture, and yet more in the delivery system.

The cycle of surveys and reports continues. Most recently, The Disabled Living Foundation was prompted by the flow of consumer problems to undertake a new initiative to improve the provision. Their approach, in line with other recent governmental actions, was to release a consumers charter " Orthopaedic Footwear: A Quality Issue" (DLF, November 1991). This was done with support of the NHS. At the launch meeting, representative patients described their frustrations with a system

which require multiple visits to the hospital for fitting, offered little choice and produced ugly shoes which often were not functionally satisfactory. In many cases, the entitlement to shoes was being denied, clearly on a cost basis. The quality of the shoes and the quality of the service delivery were equally criticised. The charter lays out the standard of product and service which the consumer should expect: it was felt that this probably could not be met within the current system. Changes are required both at the NHS administrative level and within the manufacturing contractors. The consumer charter is perhaps timely, coming at the time of a major reorganisation of the NHS funding and structure. Discussion between the DLF and the Centre of Responsibility for Rehabilitation Products continue at this time, and the DLF has also opened discussions with the Orthotists and Prosthetists Training and Education Council (OPTEC) and those about to launch the new degree in Prosthetics and Orthotics at Salford university, in order to improve the current situation.

1.6 POSSIBILITIES FOR ORTHOPAEDIC FOOTWEAR DESIGN

In orthopaedic footwear, the stages in manufacture are

- measurement of the foot
- production of the custom shoe last
- production of the customised shoe insert if required
- production of the shoe upper
- lasting the shoe upper and adding the sole

In these processes, the most important parts for CAD/CAM technology to tackle are the design and production of the shoe last from foot measures, and the design of the pattern pieces for the shoe upper, and design and production of the insert. These are the stages where information from patient measures must be integrated into the customised component design. Variability of quality and fit is most difficult to control in these processes, and the majority of the manpower time is spent in their execution. Fabrication of the shoe, both in the closing (piecing together) of the upper or in the lasting is of less importance: good shoe-making practice can produce reliable results, and some automated machinery (eg. machine lasting) can already be introduced on an ad-hoc basis.

A CAD/CAM solution to the design of the basic shoe, less customised inserts which can be regarded to some extent as a stand-alone problem, was proposed by the author previously in an application to DEC/Times Higher Educational Supplement "Technology Challenge '87" (Lord, 1988). Figure 1.8 demonstrates the hardware of the main operations and suggests the value of using Information Technology to enable rapid communication to a central fabrication site (based on the then current range of DEC computing equipment).. Foot measurement data is transmitted to the centre where an appropriate last can be designed by the orthotist/last-designer at a computer console. CNC (computer numerically controlled) machinery used to manufacture its physical realisation, which is needed as a mold during shoe fabrication. The shoe upper style is developed in the computer over the last model, and then the pattern pieces are cut out on a plotter-type device.

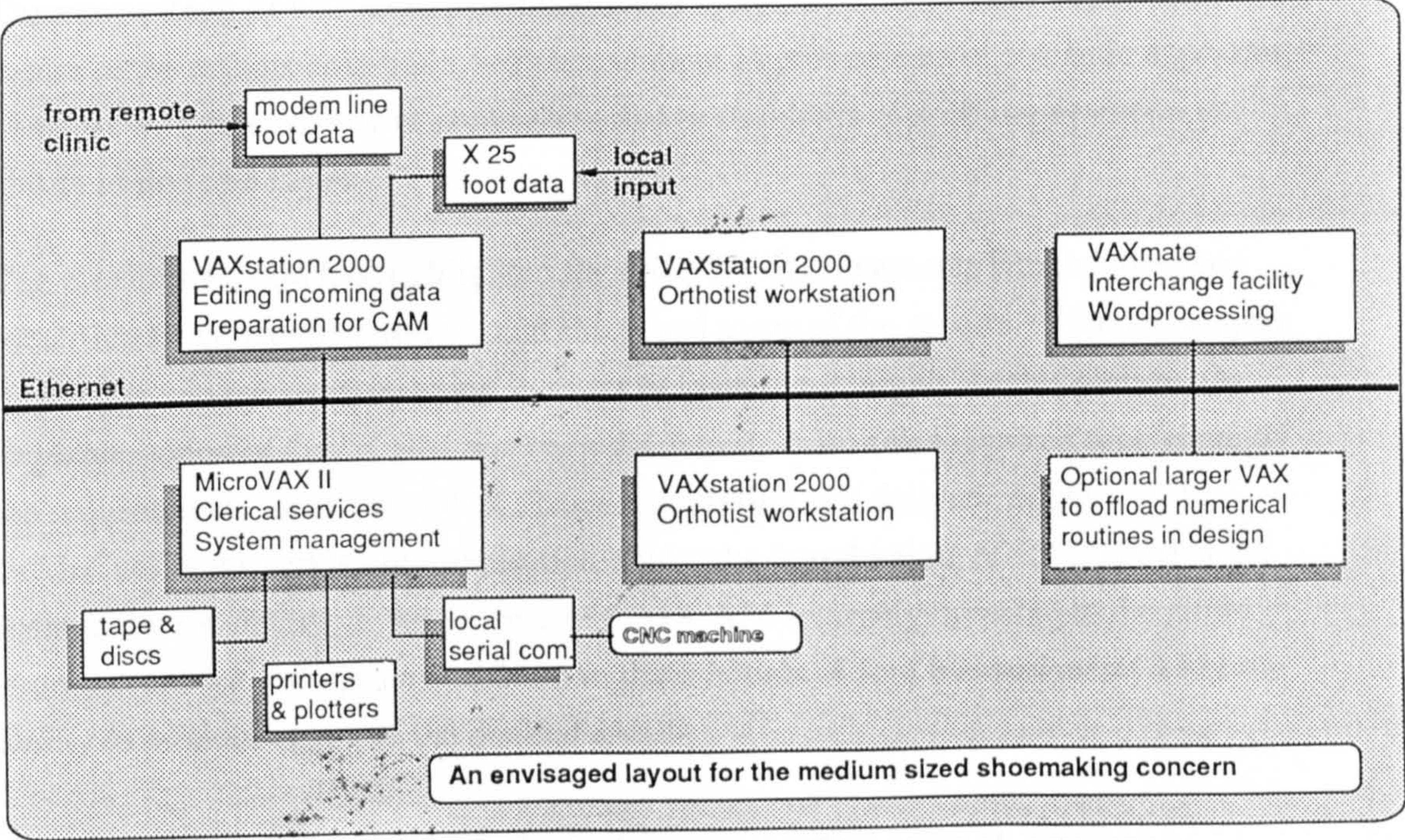
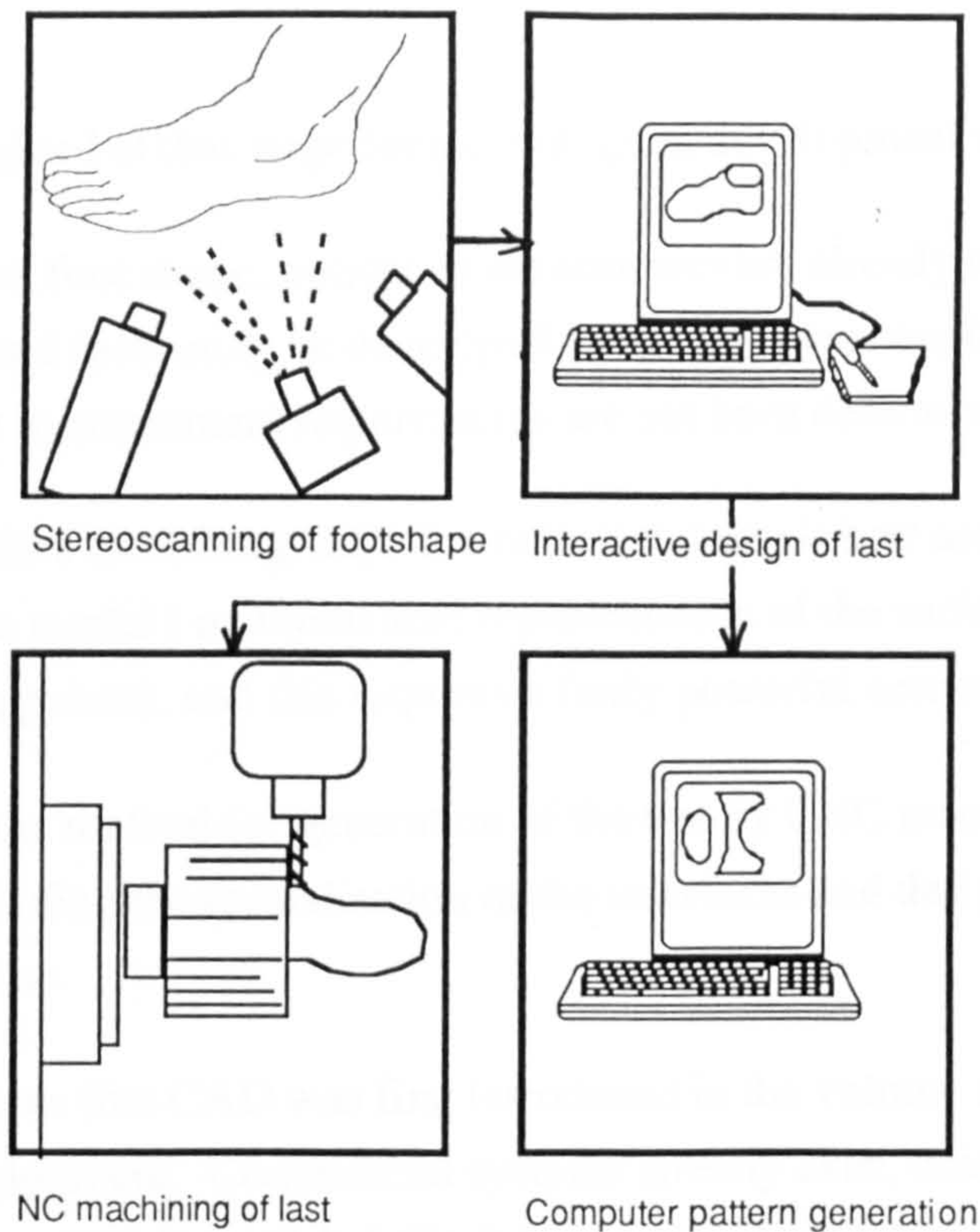


Figure 1.8. Basic operations for orthopaedic footwear design, and implementation of a network using the Vax computer range from DEC.

Areas which were highlighted at that stage for technological development were

- i) the digitisation of foot shape: optical shape scanners are already used for body shape definition, and these may be developed for the footwear application, although the exact measurement requirements are not been determined
- ii) interactive surface modelling: adjustment to last shape is best accomplished by use of a surface model (mathematical representation of the surface through the measured data points), and this requires a fairly powerful computing facility
- iii) last-making: the method for generation of the last by CNC machine needs investigation, including the formalisation of the interfaces and design of an appropriate machine.

It is also appropriate to note that CAD was first introduced in the volume shoe trade to facilitate shoe style development. Commercial systems already exist, notably Padsy from Atom Vicam, Shoemaster from C & J Clark International, and the Gerber-Camsco system. It was anticipated that these systems could be adapted for the one-off nature of the orthopaedic trade, with consequent improvements in cosmetic appearance and also with consistency of styling to achieve standards of such requirements as ability to don and fasten.

The previous section has highlighted the areas for improvements which have been identified by consumer surveys, and discussed some of the reports which are largely directed at service reorganisation in order to meet these targets. In this section, the implementation of CAD/CAM has been discussed. It is now suggested that some of the requirements for improved fit , cosmesis, styling and delivery might well be tackled not in the service reorganisation but by the introduction of CAD/CAM at the manufacturers. Although the process of CAD/CAM is largely invisible to the clinic team, except for perhaps an alteration in the methods of foot measurement, it has the ability to produce many of the desired results.

CAD/CAM Philosophies and their Impact on Functional Success

Now that technical feasibility is demonstrated for prosthetic and orthotic applications, wider issues have begun to emerge. The market is being opened up by new systems which offer different philosophies of operation, different hardware platforms, different combinations of functions and additional features(Lord & Davies, 1988). The choice

of system is now influenced by factors beyond that of technical capability which was been pre-eminent at the onset.

Consider the longer established procedure of CASD (computer-aided socket design). The UCL system and the early MERU system were the first to be developed for clinical trials . These differed very fundamentally in their basic concept. This difference arose in the method of generating the basis for the socket model. The UCL system requires the shape of the residuum to be captured into the computer, and then proceeds to *transform* this shape by predetermined algorithms to produce the socket features. In contrast, the early MERU system required only a few key dimensions to be measured from the residuum, and then proceeded to scale a *reference* socket shape to match these dimensions. In either system, the basis model thus generated could be further adjusted if required by graphical interaction, what might be termed 'on-screen sculpting' .

The implications of this difference are manifest in several ways. In hardware terms, the reference system is preferential, requiring a minimum of only a simple caliper device to take the few measures to allow scaling of the reference socket. The transformation system in contrast requires some method of digitising the complete shape of the residuum. This can be done as an optical scan of the residuum, which is ideal in the sense of being a non-contacting method which does not distort the limb. Also methods of triangulation with laser light have been developed which are able to acquire the coordinates of thousands of points over the complete surface of the residuum in seconds (Fernie et al, 1984) or alternatively a silhouette method has been employed in the scanner developed at the Bioengineering Centre (Crawford 1985). However, these systems are costly both in terms of the capital and installations required. Early trials of the UCL transformation-based system were performed by taking a conventional plaster-wrap of the residuum, and then digitising the internal shape with an instrument with a small wheel that spirals around and up from the tip to the proximal edge.

The simplicity of the hardware requirements reference system is offset by a need for far more expertise built into the assumptions and software. In the choice of the measurement locations, many questions are raised such as how many and which measures are necessary to characterise adequately the residuum shape, how should the reference socket scaling be achieved, and how many reference socket shapes are required to match the population of residua to a reasonable accuracy and how should the appropriate one be selected. The honing of such a procedure might be expected to take many years of controlled experimental use to refine this seemingly simple

measurement & scaling system, as it did in the roughly comparable development of 3-dimensional grading systems for commercial shoe lasts. Refinements of this type are reported by Torres-Moreno et al 1989. In comparison, the transformation system starts with a shape which relates more closely to the required socket dimensions.

Furthermore Dewar et al (1985) were able to establish a fairly robust transformation algorithm in their work on lower-limb prosthetics, by comparison of shapes taken from the original plaster-cast of the residuum with the shape following rectification of that plaster-cast by traditional hand craft methods. This takes the form of a rectification map, stretched over and around the stump shape and anchored to the distal tip and the patellar tendon region, which then delineates regions which are either built up to provide relief in the final socket, or reduced to ensure a positive interfacial pressure between the residuum and socket.

Finally, in terms of the consistency and reproducibility of the process it is necessary to consider how close to the final solution is reached in each case by the automated procedures and how much work is subsequently needed to obtain satisfactory customisation. It is acknowledged that the automated procedures of both methods may not be able to produce the ideal socket due to individual abnormalities such as tender tissues, irregular contours etc. Also the prosthetist may need to exert his judgement on the degree of rectification depending on how bony or fleshy the residuum is, although to some extent this can be accommodated in the reference system by choosing different reference models and in the transformation system by applying severity of rectification in the various mapped regions. Finally though, a facility is usually provided to enable free-form shape modification on the screen - 'on-screen sculpting'. The provision of on-screen sculpting to allow final surface modifications is a mixed blessing. Whereas it may help the prosthetist to feel secure that he has ultimate freedom to generate any shape he wishes, in practice he may not be able to control the shape adequately during this stage. The quality advantages of a systematic automated rectification can be rapidly lost once the surface is modified by sculpting. Indeed performing this craft process with reference to a 2-dimensional computer screen is certainly more difficult than having the positive in the hand. In early trials of the MERU system conducted at the Bioengineering Centre, there was a fairly high dependence on on-screen sculpting to achieve a satisfactory result.

The introduction of two further software applications for CASD serves to demonstrate the very different natures of the products that can be developed ostensibly for the same purpose. The Shapemaker package from Seattle, USA, introduced a different type of generic shape manipulation software, which can in principle be used for any sockets or body orthotic application. Whereas the preceding two packages from UCL and

MERU were designed and subsequently marketed as complete systems tailored for prosthetic practice (including patient record handling etc.), the Seattle system purports to be solely a shape editor. This leaves the prosthetist free to arrange his own filing system. The package also introduced an innovative concept of user-defined rectification maps through a facility to generate templates locked to specific anatomical landmarks. The Seattle package aims for conceptual simplicity of a single function - shape editing-, wide general application areas and ease of use. The Mex package from researchers at Strathclyde University, Scotland, presents another very different system. Running under a metafile executive, this application can readily be tailored to present different levels of functionality (and complexity) for use in the experimental, teaching or clinical environment. It has the infrastructure expected in a commercial CAD/CAM system which allows, for example, output drivers to various standard CNC machines (computer-numerically controlled) and, because it runs on a graphics workstation as opposed to the PC type platform of the other systems, it has fast and elegant graphics. In basis however it provides similar transformation capabilities to the Seattle and UCL systems.

For an example of philosophy of function in orthotics, the developments of both orthotic insoles and special seating have introduced the issue of standardisation of load-bearing during shape capture. This issue has been a long-standing topic of debate in casting for orthopaedic footwear, where local preference dictates unweighted, semi weight-bearing or full weight-bearing conditions. In practice, the subsequent modifications made to the casts are probably adjusted to the weight-bearing conditions at the time of casting, so that the end result may not be greatly different, although this is contentious given the variation in flexibility and geometry of each foot. With the introduction of the more quantitative approach of CAD/CAM, the interactions of the measurement conditions and the subsequent modification procedures can be explored. In seating, it is clearly impossible to take a meaningful unloaded scan, although there are clearly different approaches which allow degrees of surface adjustment at the time of capture. These allow the operators perhaps to mimic the various procedures with which they are currently familiar. Some standardisation may evolve in time.

In conclusion, it is clear that the concept that the developer have in mind at the onset can result in packages which differ in more than just detail. It has been demonstrated that two different approaches emerged early on to the generation of socket shapes, which have been termed here the reference shape approach, and the transformation approach. The implications of these two approaches are profound, in terms of the hardware and information engineering requirements. The environment of

the developers - educational, clinical, computing, engineering - may also affect the product, with some systems clearly aimed at the end user, while another can cater for the variable demands of research and training, and the sophistication in terms of the software approach is strongly influenced by the skills of the development team and the environment. The local perception of needs has influenced the developments, for example in the provision of a generic programme in the American market, where it is assumed that matters such as filing and retrieval of data will be adequately set-up under the normal operating system by generally computer-literate prosthetists. The very basis of these example prosthetic systems has been influenced in ways that might not always have been consciously predetermined in advance of the developments.

Implications to Quality and Service Delivery

British Standard BS 5750 now governs the quality of product design and manufacture in the UK. In a nutshell, BS 5750 requires that product development is conducted in such a way as to 'assure quality throughout the design, production, installation and servicing'. The same standard can apply to orthopaedic footwear, although the terms 'installation and servicing' sound a little odd in this context and might be rephrased as 'fitting and repair'. The code requires industry to develop properly controlled and documented procedures, where quality is assured throughout rather than being consigned to a process of inspection and rejection at the end of the line. The current problem is **not** that the best shoemaker cannot provide a very good solution for any individual patient; it is that this standard is impossible to guarantee for the vast majority of patients at a reasonable cost.

Quality in terms of BS 5750 has been described as 'fitness for function'. For orthopaedic shoes, this certainly implies that they must meet the prescribers requirements for accommodation or correction of deformity. In that sense, the primary consideration is the fit of the shoe. Problems of fit occur at the stage of transfer of information on the specification from the fitter to the factory, with interpretation of the measurements into shoe lasts and shoe uppers, and with conveying the results of trial fit back as a basis for adjustments to the last & uppers. The bygone days where a single craftsman measured the foot and made the shoes are not an economic feasibility.

From the patient's viewpoint, quality will also include aesthetic considerations. Indeed if the patient regards the shoes as ugly and refuses to wear them, then they are not fit for the purpose. Within the craft system there are many difficulties in pursuing stylish shoes. The patient may not like a chosen style when adjusted to his or her own (oddly-shaped) last: the choice of leathers is limited by costs of maintaining stocks: the pattern

cutter will probably not have a sure sense of fashion: with only one or two pairs provided a year, the patient might be too cautious to try anything different.

Quality is thus difficult to control in a cost-limited craft-based system of production. A primary advantage foreseen in the introduction of CAD/CAM technology is improvement in quality. A more quantitative approach to measurement and design of shoe lasts & uppers could alleviate the fit problem.

Through the developments of advanced design and manufacturing techniques the consumer can expect faster response, high-street standards of styling and even cooperation with the high-street manufacturers to get style ranges available concurrently, and consistent quality of fit provided through a quality-controlled procedure.

1.7 DESIGN OF THE THESIS

This thesis represents a design study of the factors involved in the development of an effective CAD/CAM system for the design of orthopaedic shoes. Figure 1.9 shows a block diagram which identifies the factors which have been included under two headings: Fundamental Studies provide the necessary background information, and Applied Developments represent investigations into the CAD/CAM processes. The relevant chapters for each are noted. Because the development of CAD/CAM is a major undertaking that will continue for many more years, the thesis represents a snapshot of the progress to date. Some parts of the work are completed, and other parts have been initiated and are in progress. No doubt there will be many future developments in many areas related to this study particularly related to the design of shoe last shapes, standards of pattern styling and hardware for foot measurement and last manufacture. The deliverables of the work described in figure 1.9 should be

- a contribution towards the definition of needs for improvement in the supply of orthopaedic footwear (Chapter 2)
- fundamental understanding of the measurement and interpretation of plantar pressure distributions for the purpose of insert manufacture (Chapter 3)
- basic considerations of the influence of shoe design on shear (Chapter 3: in progress, work continues as a separate PhD programme)
- a contribution toward the generation of insert shaping from plantar foot shape (Chapter 4)
- experimental verification of CAD for style transfer and pattern generation (Chapter 5)
- an integrated design system for generation of shoe lasts and shoe (Chapter 6: in progress as Eureka project SELECT due for full-scale industrial trials in 1994, and as a separate PhD programme on shoe fit parameters)

In a project of this complexity and of such an interdisciplinary nature, it is obvious that collaboration is needed. In the text, the role of the author is made clear by the

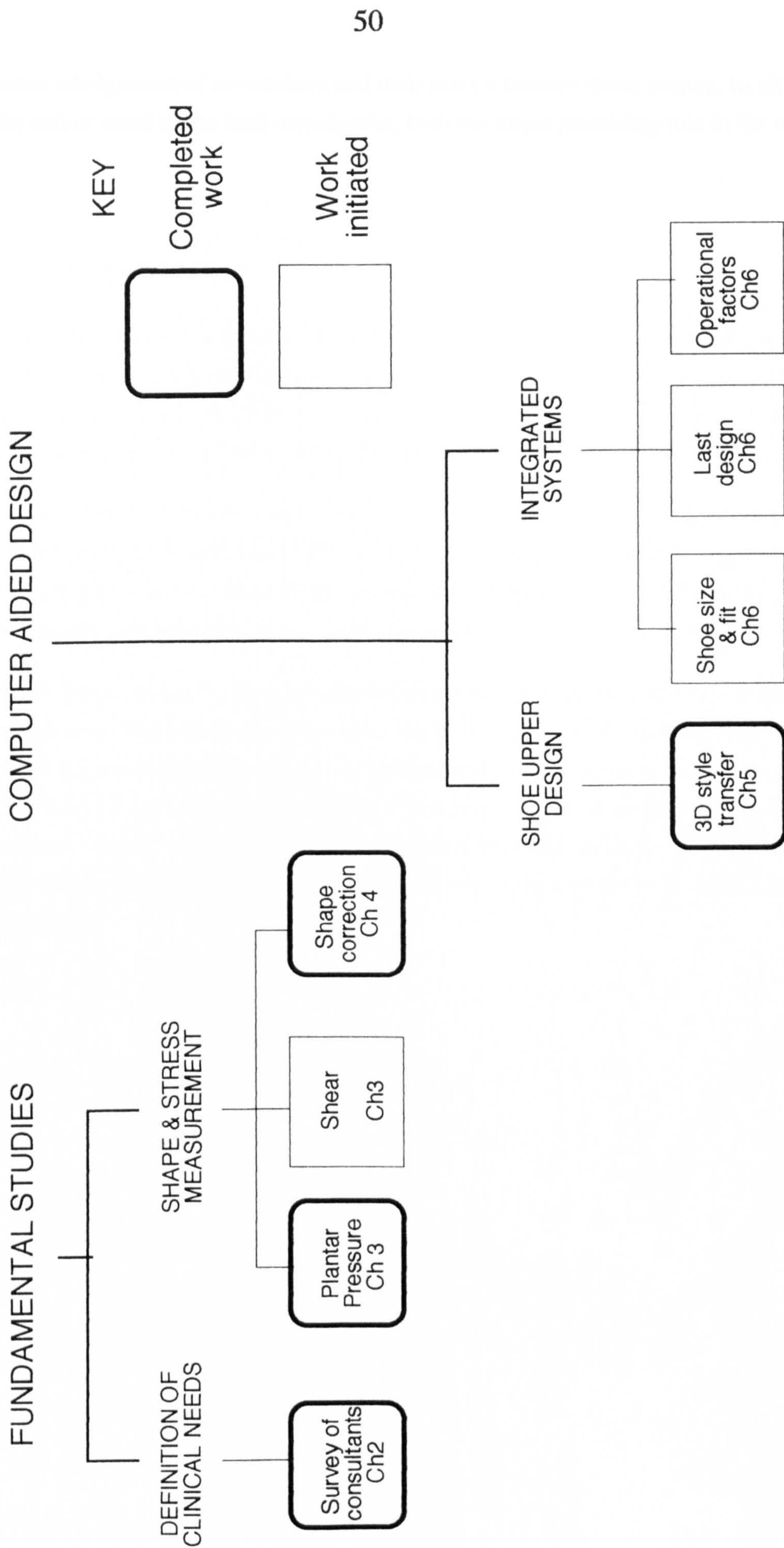


Figure 1.9 Diagram showing the interconnection of areas of work in the thesis

acknowledgement of co-workers and their roles wherever these existed. In all cases, the author acted as the lead investigator, with the major practicing role in the work.

1.8 SUMMARY

Computer-aided design and manufacture is now accepted as a realistic option for the production of orthopaedic shoes. Developments for other related body support applications have been rather lengthy, but the technology is now sufficiently developed that an acceleration is being seen in the introduction of these advanced technologies.

The clinical need for orthopaedic footwear is increasing due to demographic trends and life-preserving advances in medicine. At the same time, consumers are rightly demanding an improvement in the provision of orthopaedic footwear. To do this with reasonable cost will require a switch in both technology and service delivery models.

CADCAM systems can be implemented in many different ways depending on the design brief. Different approaches may make fundamental assumptions which deeply affect the resulting functional success. These lead to very different technological needs. The design brief cannot be evolved in a narrow sense, but must start with consumer market research, a thorough understanding of the service delivery, and a wide knowledge of all related CADCAM applications in the medical field and in general industry.

CHAPTER 2. A SURVEY OF CLINICAL REQUIREMENTS

2.1 BACKGROUND

Employing high technology techniques in a largely craft-based industry will almost certainly necessitate a fairly radical reorganisation of the UK delivery system. It was considered advisable to gather as much pertinent data as possible about the current footwear delivery system, both to understand the starting position and to target the computer system at areas of greatest clinical need and potential profitability.

This requires understanding of the system from the viewpoint of
the patients,
the industry and
clinical staff involved in the supply system.

It has already been established that patient dissatisfaction leaves room for improvements appropriate for a CAD solution. The present survey is confined to investigation of the footwear supply system from the point of view of the clinical staff. Furthermore it was decided to elicit information solely from medical and surgical consultants involved in footwear prescription. The survey is thus an overview of consultants' perception of the existing patient load and supply system.

2.2 SURVEY DESIGN

Circulation

A questionnaire (Appendix I) was sent to United Kingdom hospital consultants in diabetics, orthopaedic surgery and rehabilitation and rheumatology. Only consultants were targeted since they alone may prescribe footwear within NHS hospitals. These particular disciplines were chosen after discussions with several senior consultants although it was mentioned that other staff, such as paediatricians, may also occasionally prescribe footwear.

A decision to send out the questionnaire to all consultants rather than a sample population was based on an expected response rate of 20% or less. The provision of footwear is said to be variable across the country, and therefore to obtain significant results by regions it was necessary to poll all consultants.

Correspondence address labels were supplied by the British Diabetic Association for consultant diabetologists and the British Orthopaedic Association for consultant orthopaedic surgeons, to whom we express our thanks. Home address labels of the consultants in rheumatology and rehabilitation were obtained from the database of The Medical Directory. A senior member of each of the three professional groups advised us on the design of the questionnaire and their names were added to the covering note on the first page which briefly explained the purpose of the study. They also wrote separately, encouraging recipients to complete and return the forms. A Freepost envelope for the return of completed questionnaires was included in the outward mailing (which was slightly disrupted by the postal strike in the Summer of 1988).

Question Design

The questionnaire was designed to fit onto four A4 size pages. The first page explains the purpose of the questionnaire, leaving only three pages for questions. This was a compromise between the large space required to ask all the questions that were wanted, and the size of questionnaire that consultants could reasonably be expected to complete. The list of potential questions was reduced to those which might potentially yield the most relevant information for our CAD/CAM work.

The required response to each question was restricted to one or more ticks, to reduce errors in subsequent transcription of the responses onto the data base. A short space for comments was left at the end of the form. The first section of the form (Background Information) requested a minimal amount of information in order to

determine differences between the type of patients seen by the different disciplines; it also requested the NHS region for the respondent. Due to our error in using an incorrect regional list, East Anglia was omitted from this list, and the category Manchester was provided rather than the two separate regions of Mersey and North Western (apologies offered to those recipients who were inadvertently slighted by these omissions). Scotland was arbitrarily divided into 5 areas of roughly equal square mileage, and it is noted that three of these (North Scotland, Grampian and Tayside) are very small in comparison to the other areas. A list of areas is shown in Figure 2.1.

Area	Health Boards
<u>Scotland</u>	
N Scotland	= Highlands, Orkney, Shetland, W. Isles
Grampian	= Grampian
Tayside	= Tayside
W Scotland	= Argyll&Clyde, Glasgow, Ayrshire & Arran, Dumfries & Galloway, Lanarkshire
SE Scotland	= Borders, Lothian, Fife, Forth Valley,

Northern Ireland

N. Ireland = Northern, Eastern, Sourthern,
and Western HSSB

England

All areas as NHS regions except:-

Manchester = Mersey , North Western.

Figure 2.1 Mapping of Health Boards in Scotland, SHHBs in Northern Ireland and NHS Regions in England into geographical areas.

The second section relates to the current organisation of the delivery service within the hospital; and the third section asks a question regarding delegation in an ideal world; and the last section deals with the perception of various aspects of the service, such as costs, speed, and satisfaction.

2.3 RESULTS and ANALYSIS

Response Rate

A total of 1696 questionnaire forms were sent out and 821 (48.4%) were returned by a date subsequently set by us as a suitable cut-off point for the analysis of results. There were 25 forms returned after this date and 6 forms returned because they were originally sent to inappropriate targets (Republic of Ireland, retired consultants, consultants inadvertently listed by incorrect discipline).

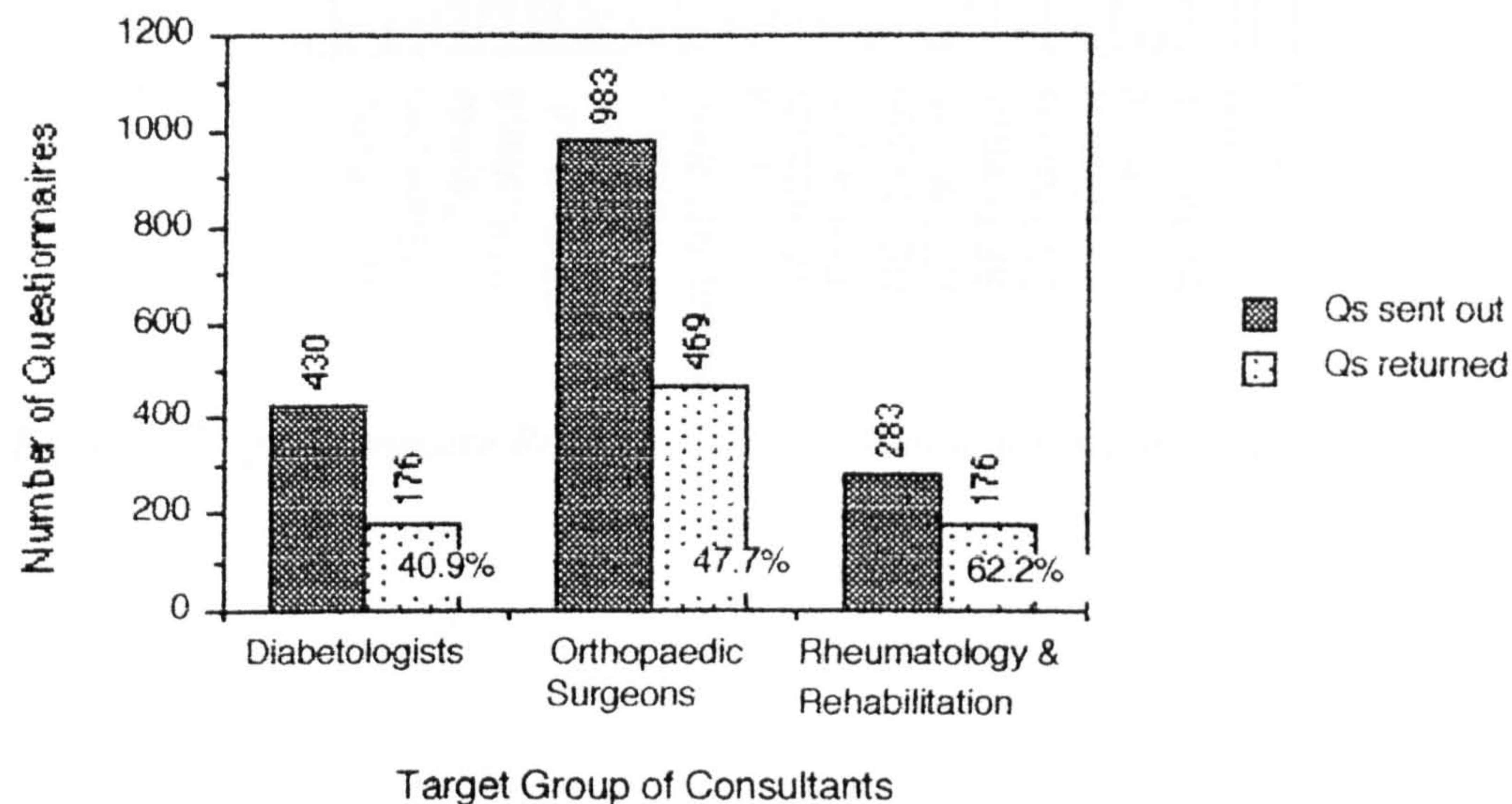


Figure 2.2 Response Rates.

Figure 2.2 shows the responses from the individual professional groups, with response rates of 40.9%, 47.7% and 62.2% for diabetologist, orthopaedic surgeons and consultants in rheumatology or rehabilitation (who will henceforth be lumped together under the term rheumatologist for sake of brevity). The rates were gratifyingly higher than expected and give sufficient data to allow a sensible regional analysis to be undertaken on the whole, Figure 2.3; only the number of responses from North Scotland, Grampian and Tayside are low at between 5 and 10.

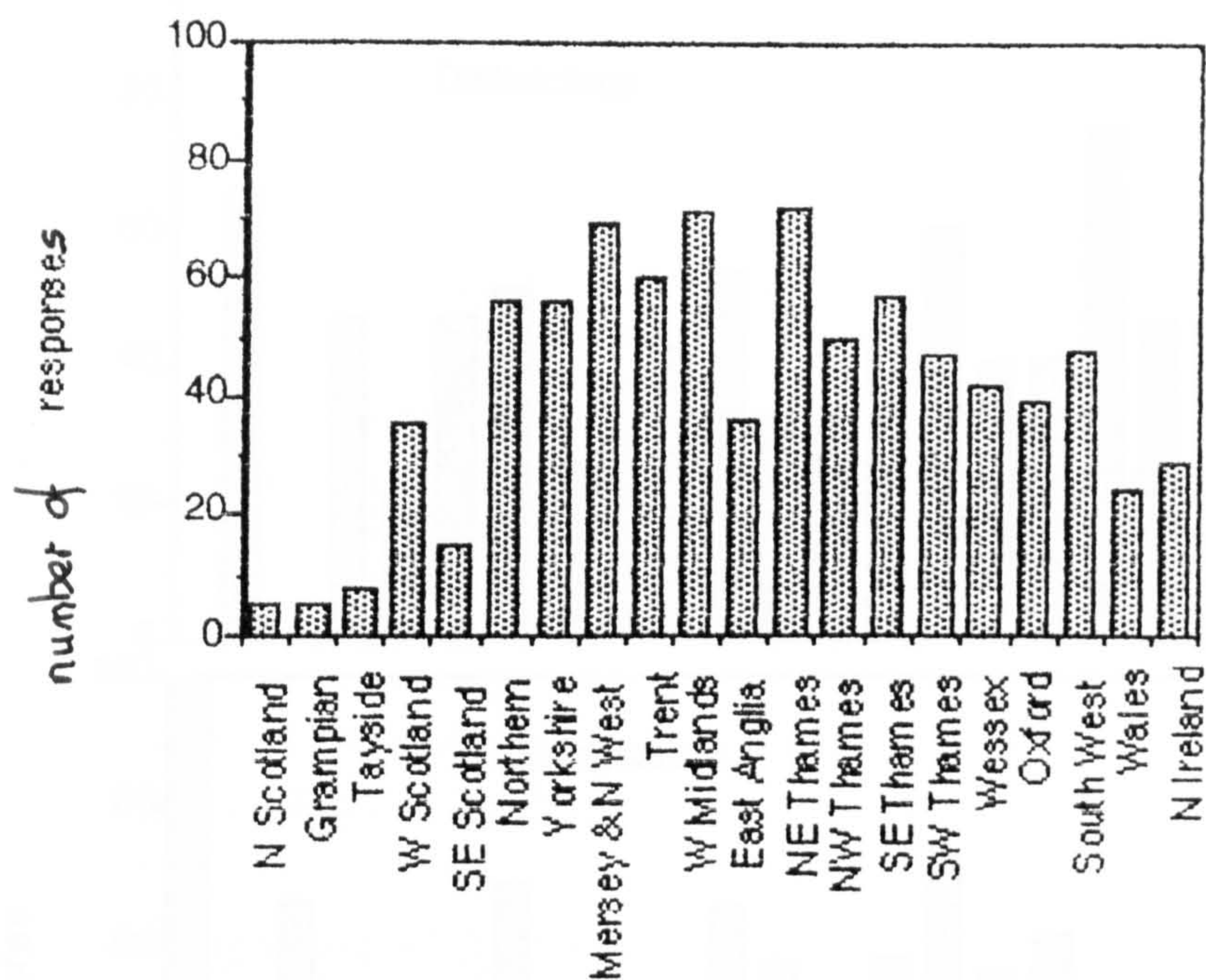


Figure 2.3. Questionnaire Response by Region for All Specialties

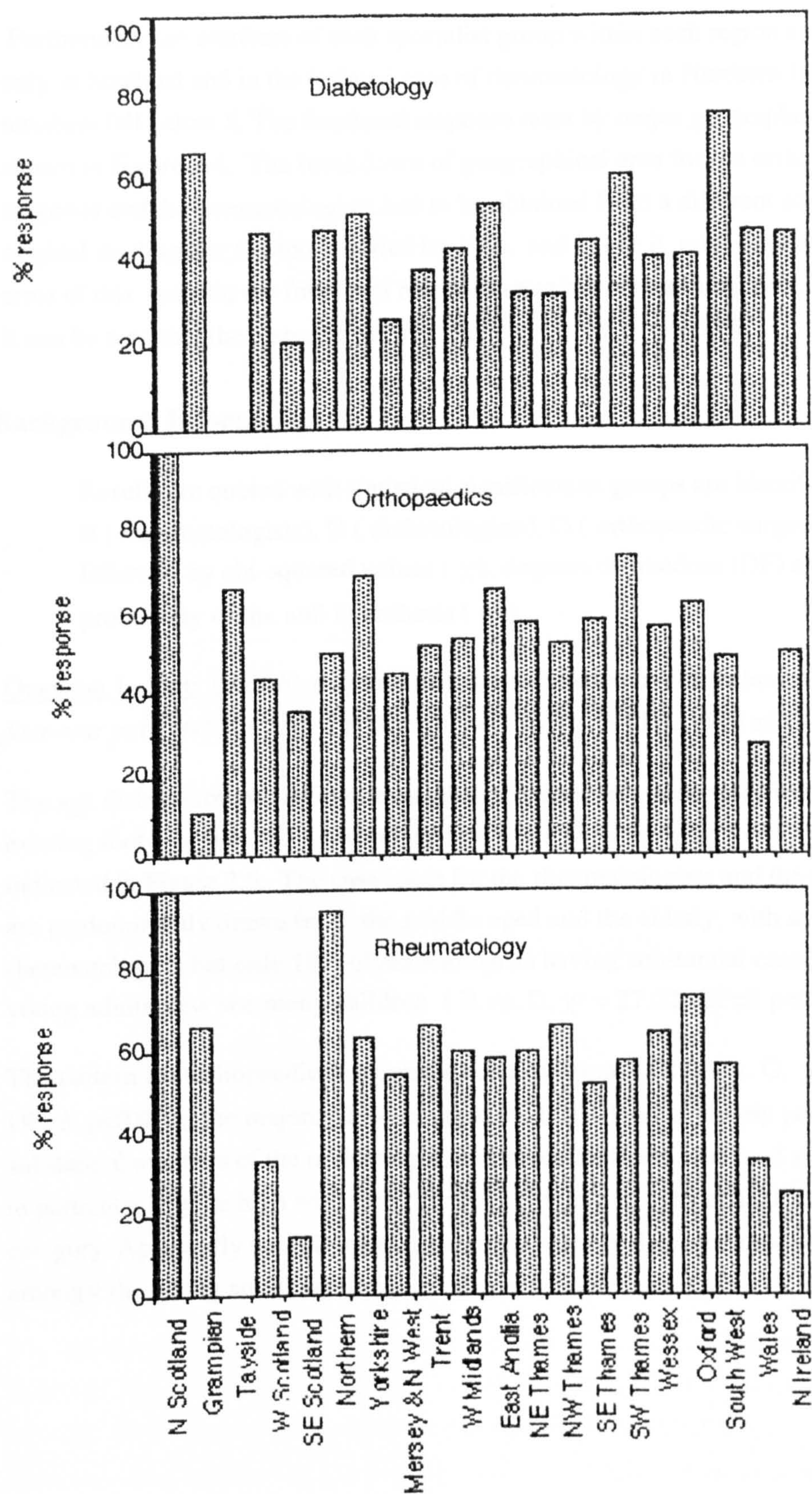


Figure 2.4. Questionnaire Response Rate by Region and Specialisation

Furthermore the numbers of each specialist group within each region are reasonable; only in Scotland and in the isolated case of rheumatology in Northern Ireland do these numbers fall below 5. The fractional response rates by major geographical area are shown in Figure 2.4. The breakdown of geographical area for the orthopaedic surgeons and the rheumatologists had to be obtained from a different source to the original mailing list; the totals varied by 10%, and hence it must assumed a margin of error of this order in the fractional response rates by geographical area. Nevertheless it can be seen that the response rates in England are all above 30%.

Background Information

Results are quoted with statistical significance: groups are identified as R (rheumatologists), D (diabetologists), O (orthopaedic surgeons), followed by chi-squared values (χ^2), degrees of freedom (DF) and probability of the null hypothesis ($p=$).

Question 1. Part: 1 *In which of these categories do you have a substantial number of footwear patients?* (Ans: Children, Young adults, Middle aged adults, Elderly > 70)

The age distribution of NHS patients needing shoes, inlays or modifications to existing footwear under the general care of consultants replying to this questionnaire is indicated in Figure 2.5. The case loads for the rheumatologists and the diabetologists are predominantly drawn from the middle aged and the elderly, with some 40% of rheumatologists but only 10% of diabetologists having substantial case loads among young adults; few see many children (R vs. D, $\chi^2 = 27.02$, DF=3 $p<0.01$)

The pattern for orthopaedic surgeons is quite different (R,D) vs. O, $\chi^2 = 197.60$, DF=3, $p<0.001$); the majority have a substantial case load of elderly patients, half see substantial numbers of the middle aged, and predictably the case load among children in particular is quite high with again about half reporting substantial loads in this category. Apparently the orthopaedic surgeon typically does not have substantial loads amongst the young adult population.

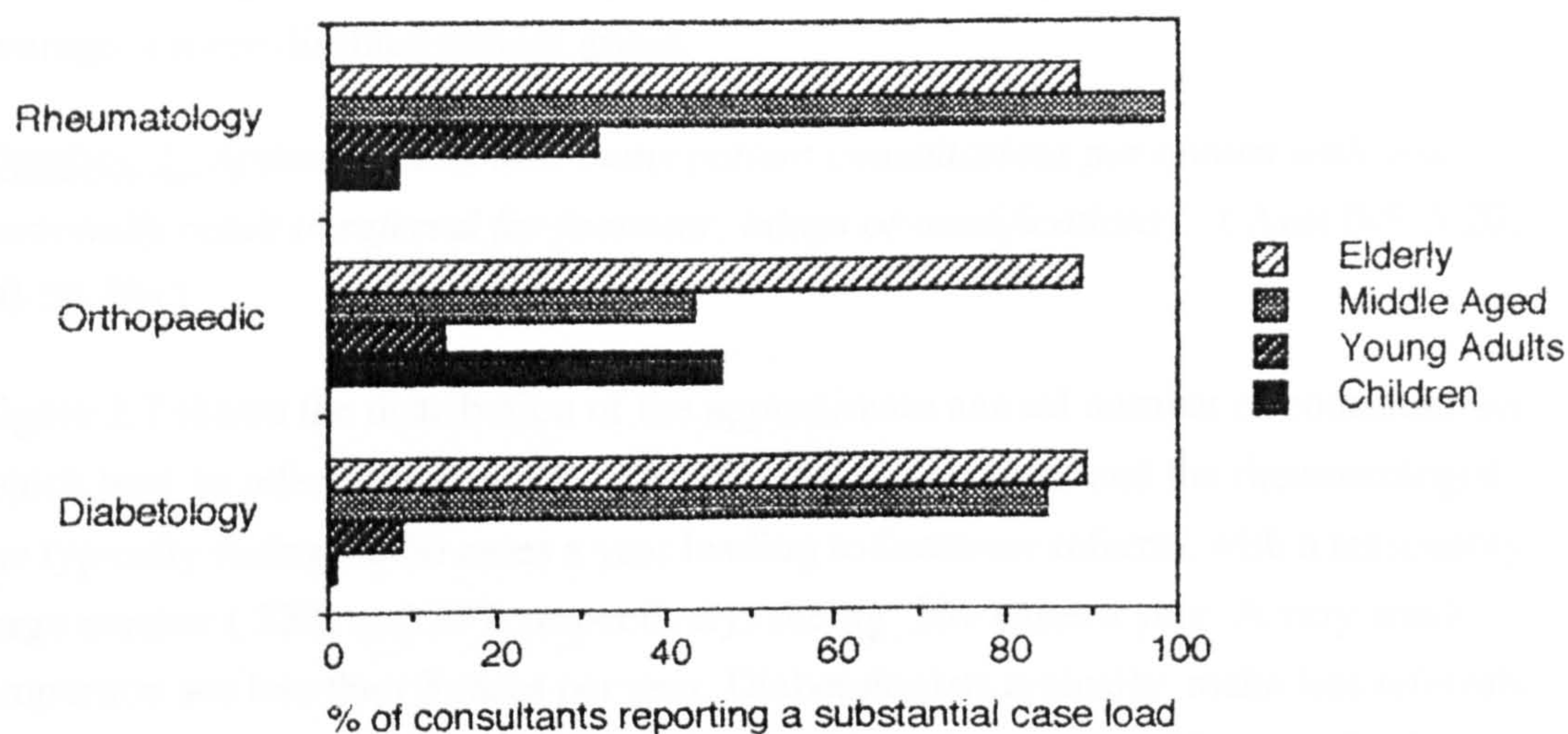


Figure 2.5. Age Distribution in the Clinics

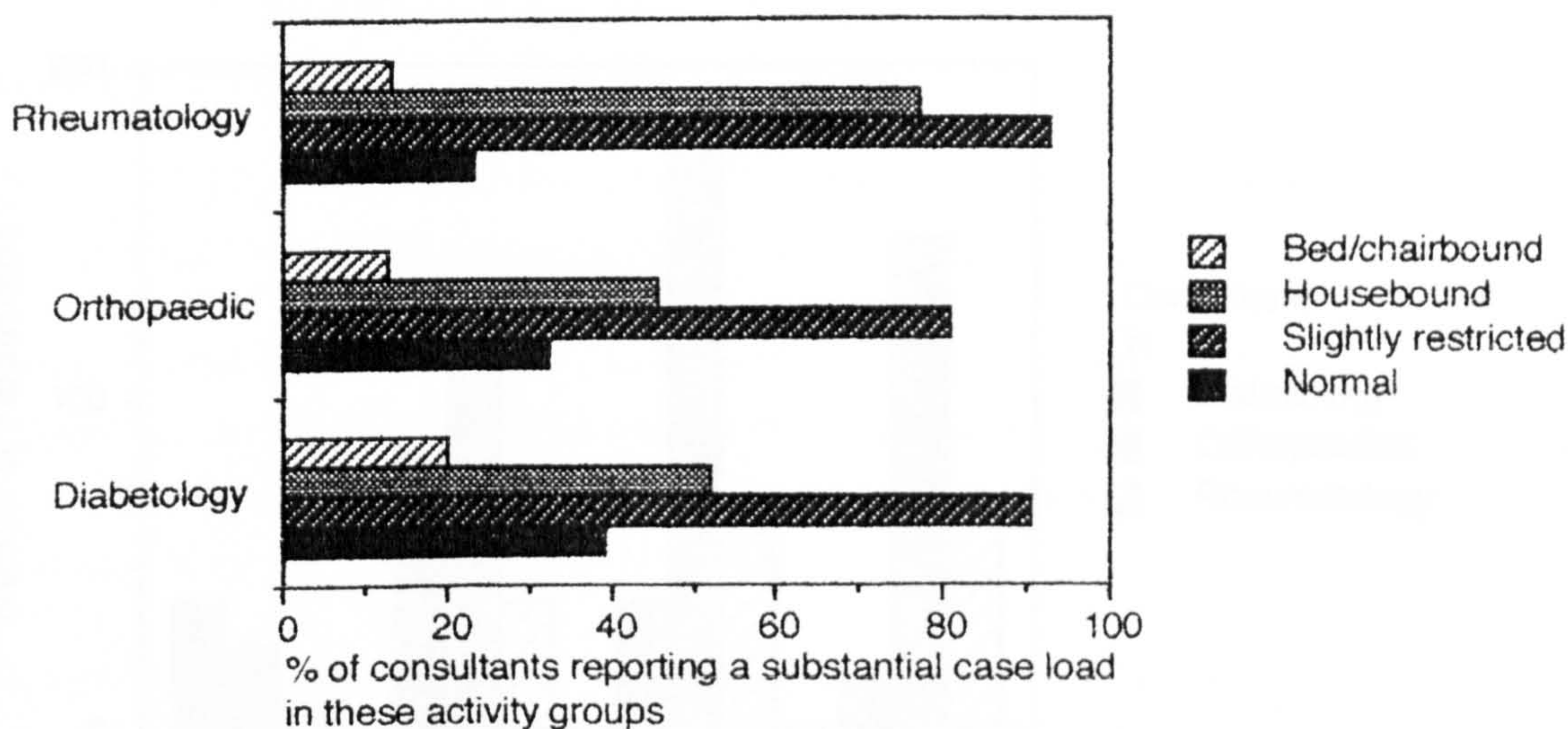


Figure 2.6. Activity Levels of Patients seen in the Clinics

Question 1, Part 2: *In which of these categories do you have substantial numbers of footwear patients?* (Ans: Normal active lifestyle, Slightly restricted lifestyle, Housebound, Bed- or chairbound)

The activity level and lifestyle of patients being seen by each consultant group is shown in Figure 2.6. The distribution of activity levels is not significantly different between diabetologists and orthopaedic surgeons (D vs. O, $\chi^2 = 2.34$, DF=3, $p > 0.5$). Most consultants are seeing the slightly restricted category of patients, with the housebound, slightly restricted and bed/chairbound categories next in that order. The pattern is different for rheumatologists (R vs. (D,O), $\chi^2 = 29.84$, DF=3, $p < 0.01$), where proportionately fewer respondents report significant case loads amongst the

normal and slightly restricted categories. The rheumatologists clinic is thus seeing, on average, a more disabled patient group.

Question 2: *Approximately how many patient consultations per annum with you personally result in referral for footwear, inlays or modifications?* (Ans: 0-5, 5-20,-20-50,50+)

Figure 2.7 shows the distribution of the approximate annual number of consultations which lead to referral of patients. The orthopaedic surgeon and the rheumatologist are typically seeing 20-50 cases a year leading to footwear referral, with a reasonably large number (32% and 39% respectively) seeing 50+ cases a year. A very small proportion see less than 5 cases per year. Diabetologists typically make less referrals each year, with an average of 5-20 per year, although some see 50+, and 20% see less than 5 cases each year.

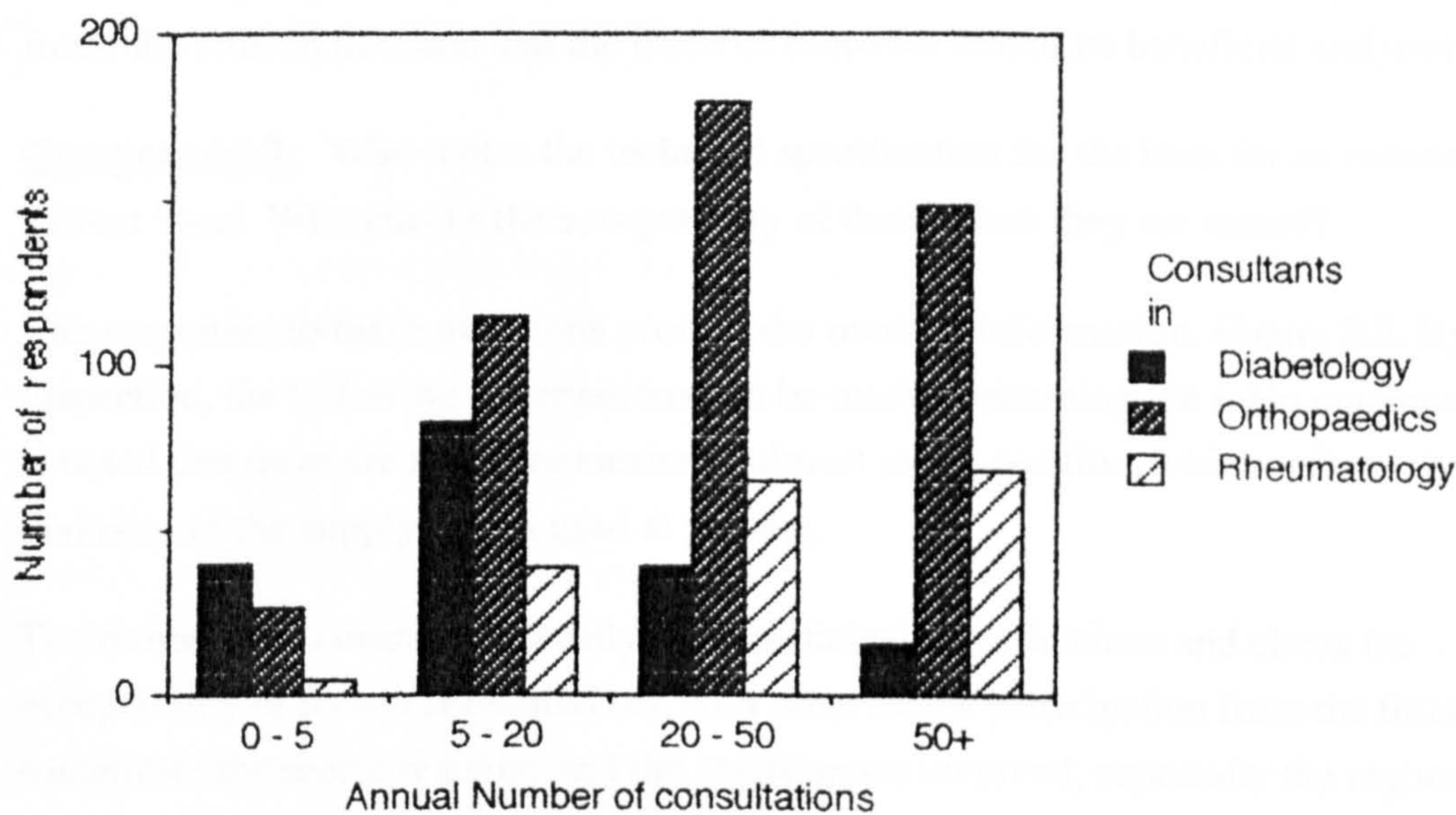


Figure 2.7. Numbers of Footwear Consultations per Respondent

Organisation in the Delivery Service

Question 4: Who first suggests that the patient may need these items?

By a wide margin, consultants mostly initiate the footwear prescription themselves. The other groups of initiators who sometimes suggest need are, in order of frequency cited, registrars, physiotherapists, or occupational therapists senior registrars and chiropodists. The ‘other’ category was ticked at about the same frequency as these

previous groups, and indicated that the General Practitioner is also often the initiator of the request for footwear.

Analysis of the 'mostly' responses for the yourself/consultant colleague answer against all other categories showed that orthopaedic surgeons and rheumatologists answered this question similarly (O vs. R, $\chi^2 = 0.6$, $DF=1$, $p>0.5$), whereas a different pattern was seen for diabetologists (D vs. (O,R), $\chi^2 = 32.9$, $DF=1$, $p<0.001$). Inspection of the raw data shows that 35.5% of diabetologists responded that the suggestion for need came mostly from someone other than a consultant, compared to around half this number of orthopaedic surgeons or rheumatologist. The third party cited by the diabetologist is the chiropodist largely.

Question 5: Who sees the patient and makes the clinical decision that these items would be beneficial and justified?

The vast majority of respondents indicate that they, or a consultant colleague, mostly made the clinical decision that the items of footwear would be beneficial and justified.

Questions 6&7: Who writes the technical specification for the item for an individual patient ? and Who checks the acceptability of these when they are issued?

The responses to these questions produced a mass of information, Figure 2.8. By inspection, the following observations can be made concerning the main outcome. It is noted that there are non-zero entries in almost every position, which reflects the diversity of the supply routes used at present.

The orthopaedic consultants mostly write technical specifications and check the acceptability of footwear themselves, with other major participation from the fitter; sometimes the senior registrar and the registrar are involved, especially the registrar at the checking stage. Rheumatologists follow the orthopaedic pattern, except perhaps with less assistance from the senior registrar/registrar. In contrast, the diabetologist responded that the fitter is most likely to write the technical specification, with both the fitter and consultant being roughly equally cited as the person mostly checking the footwear. The diabetologist employs the services of the chiropodist in both specifying and checking footwear - from the questionnaire it is not possible to distinguish whether this activity is confined to shoe insert provision - and does not make appreciable use of his senior registrar or registrar. .

Very occasionally Sometimes Mostly			Very occasionally Sometimes Mostly			Very occasionally Sometimes Mostly			QUESTION 6 Who writes the technical specification..?
3	9	84	0	3	97	0	2	9	
4	8	7	4	22	9	2	26	14	
11	14	5	5	31	4	6	13	4	
3	8	6	4	6	1	3	9	5	
8	19	19	3	1	0	7	4	2	
7	7	3	6	5	0	12	13	1	
3	4	4	1	1	0	6	2	3	
2	2	1	0	1	0	2	3	1	
									Consultant colleague/y'self
									Senior registrar
									Registrar
									Orthotist/Surgical f. fitter
									Chiropodist
									Physio/occupational Therapist
									Appliance Officer
									Other
									QUESTION 7 Who checks the acceptability..?
7	10	23	0	7	82	3	11	65	
3	1	2	4	19	6	2	17	6	
5	2	0	12	24	4	3	11	2	
2	6	47	4	15	20	3	14	30	
2	12	20	1	0	0	3	6	2	
2	7	5	3	4	1	6	7	2	
3	9	21	1	3	3	5	6	11	
2	0	2	0	1	0	2	3	1	
									Consultant colleague/y'self
									Senior registrar
									Registrar
									Orthotist/Surgical f. fitter
									Chiropodist
									Physio/occupational Therapist
									Appliance Officer
									Other
Diabetology (n=176)			Orthopaedics (n=469)			Rheumatology (n=176)			

Figure 2.8. Response data for question 6&7: percentages of respondents in each discipline who ticked the particular answer shown, eg. 26% of rheumatologists indicated that senior registrars sometimes write the technical specification for the footwear.

Overall, only 18/821 respondents reported that the person involved mostly in technical specification was a physiotherapist or occupational therapist, with 26/821 respondents using the therapists to check acceptability. Proportionately, the Appliance Officer is used more frequently by the diabetologist to write the specification, although this should be done in consultation with the fitter according to MHM 50 quoted earlier.

The data base was interrogated to determine in what percentage of cases the acceptability of the footwear was not checked by a senior doctor with the following results:

All	114 out of 821	=14%
Diabetology	56 out of 176	= 32%
Orthopaedics	39 out of 429	= 9%
Rheumatology	19 out of 176	=11%

The diabetologist is thus less likely to check the footwear personally or delegate this to a senior medical colleague. In a very small number of cases, only the Appliance Officer was ticked reflecting that in these cases no clinical staff were involved and the only check was presumably the technical inspection.

Delegation of Specification

Question 8: To whom would you delegate as first choice the detailed technical specification for footwear, orthoses and adaptations?

The responses to this question, Figure 2.9, showed that all consultant groups would most frequently choose an orthotist/fitter as the person to whom they would prefer to delegate the technical specification of footwear (around 50% of responses).

Beyond this, there are major differences in the choice for delegation . 20% of orthopaedic consultants, and 10% of rheumatology, would never opt to delegate although few diabetologists express this view (3%). A large percentage of diabetologists would select the chiropody and therapy staff, which may reflect the shoe insert and modification nature of their footwear prescription. Some orthopaedic consultants (18%) and very few diabetologists (5%) would opt to delegate to medical staff lower than consultant level.

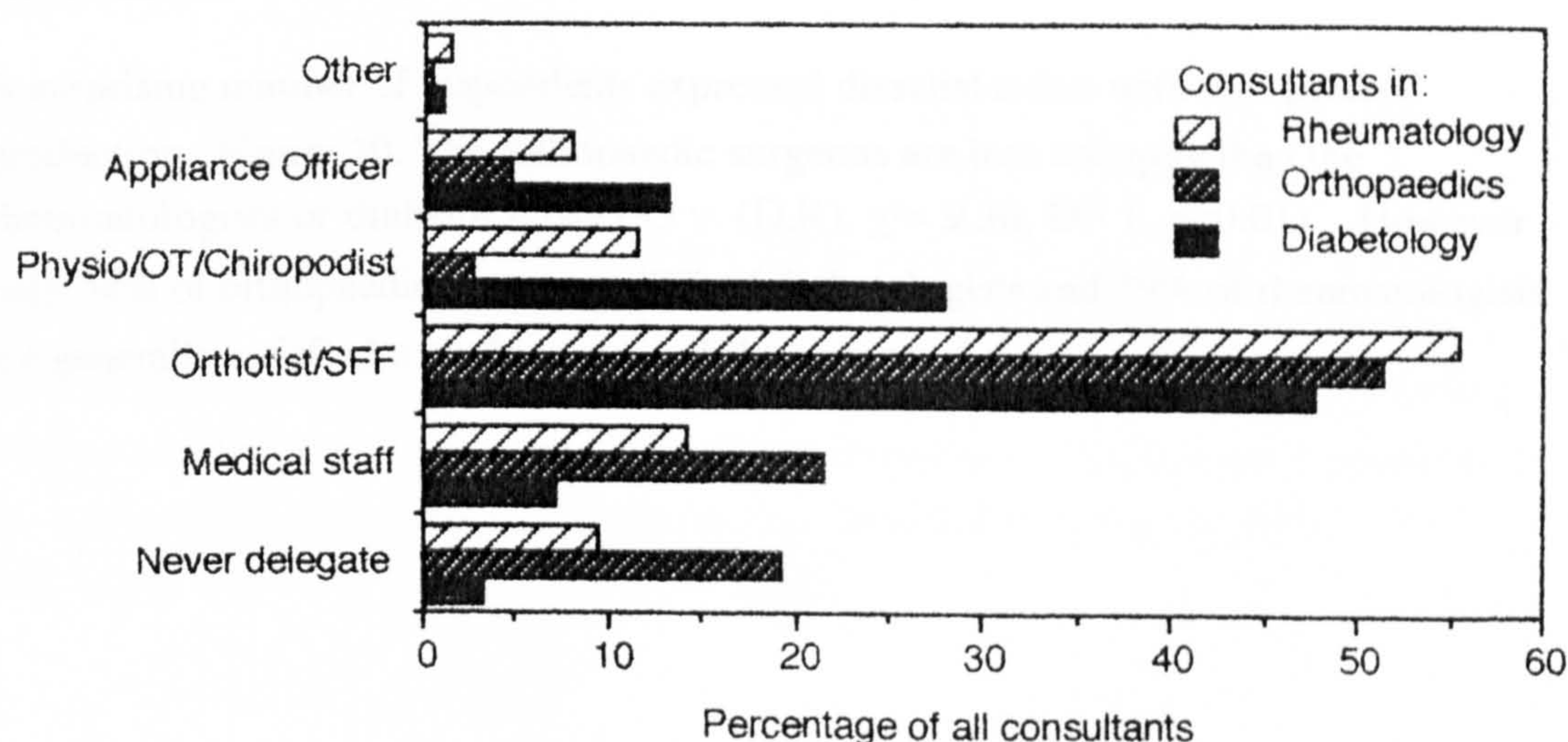


Figure 2.9 First Choice for delegation of Detailed Specification.

Perception of the Service

Question 9: What do you think is the approximate cost of a simple pair of orthopaedic shoes?

Several comments written against question 9 pointed out the ambiguous wording. The intention was to enquire the cost of a straightforward pair of *bespoke surgical shoes*; from the answers, it was clear that the cost of off-the-shelf shoes had been offered by some respondents. This ambiguity has rendered the question invalid, and no analysis was attempted.

Question 10: If requested, could you name from memory the contractor(s) who supplies surgical footwear to your patients?

The proportion of consultants who could name their contractor(s) were

diabetologists	(40%)
orthopaedic surgeons	(91%)
rheumatology & rehabilitation	(86%)

This reflects a difference in the working relationship between the diabetologists and fitters as compared to the other two groups. The diabetologist is less likely than his colleagues to have an active collaboration with the fitter.

Question 11: Are you generally satisfied with the speed of production of the footwear?

A surprising number of respondents expressed dissatisfaction with the speed of production, Figure 10. The orthopaedic surgeons are less unhappy than the rheumatologists or diabetologists (O v. (D,R), $\chi^2 = 9.30$, DF 1, $p < 0.01$). However only 54% of orthopaedic surgeons, 48% of diabetologists and 39% of rheumatologists are generally satisfied with this aspect of the service.

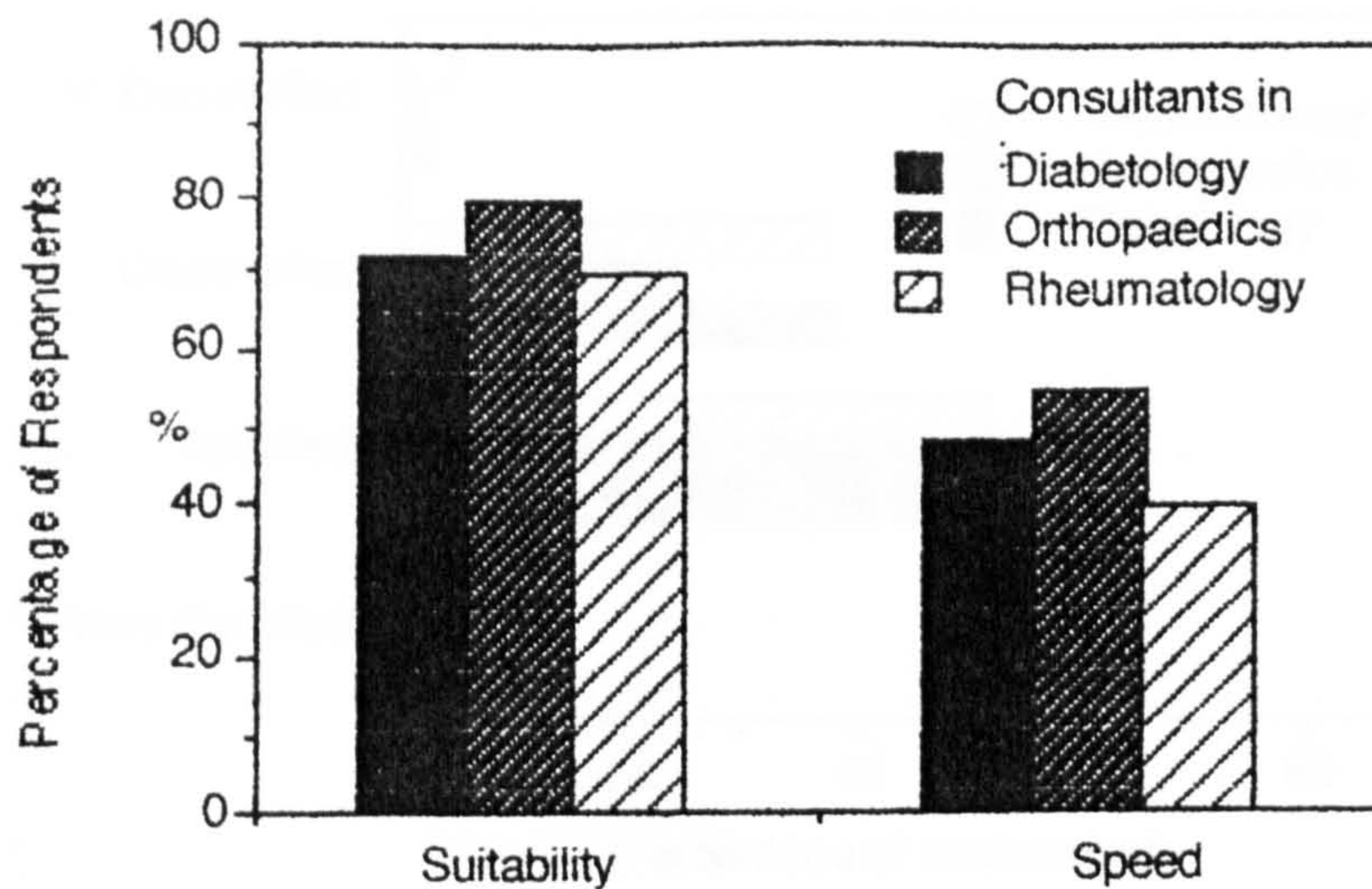


Figure 2.10. Consultant's Satisfaction with Speed and Suitability of Footwear.

Question 12: Are you generally satisfied that the footwear is suitable in practice for the purpose for which it was prescribed?

Orthopaedic surgeons are also more generally satisfied that the footwear is suitable in practice for the purpose for which it was prescribed, also Figure 2.10 (O v. (D,R) , $\chi^2 = 7.65$, DF 1, $p < 0.01$). Over 20% of all consultants are dissatisfied with the suitability of the footwear.

Question 13: What is your overall level of satisfaction with the present system for the supply of surgical footwear ? (Very satisfied, Satisfied, Dissatisfied, Very dissatisfied)

The overall level of satisfaction with the present system is significantly different between the three groups ($\chi^2 = 23.25$, DF =6, $p < 0.001$). For the diabetologists and rheumatologists there is no significant differences in the categories other than satisfied (VS vs. D vs. VD, D vs. R, $\chi^2 = 1.78$, DF=2, $0.25 < p < 0.5$). The general level of satisfaction in these two disciplines is similar with 58.5% and 57.4 % falling in to satisfied or very satisfied category. The differences lie in the larger proportion of the orthopaedic surgeons (73.3%) who ticked the satisfied category (S vs. (VS,D,VD), O vs. (D,R), $\chi^2 = 23.25$, $p < 0.001$).

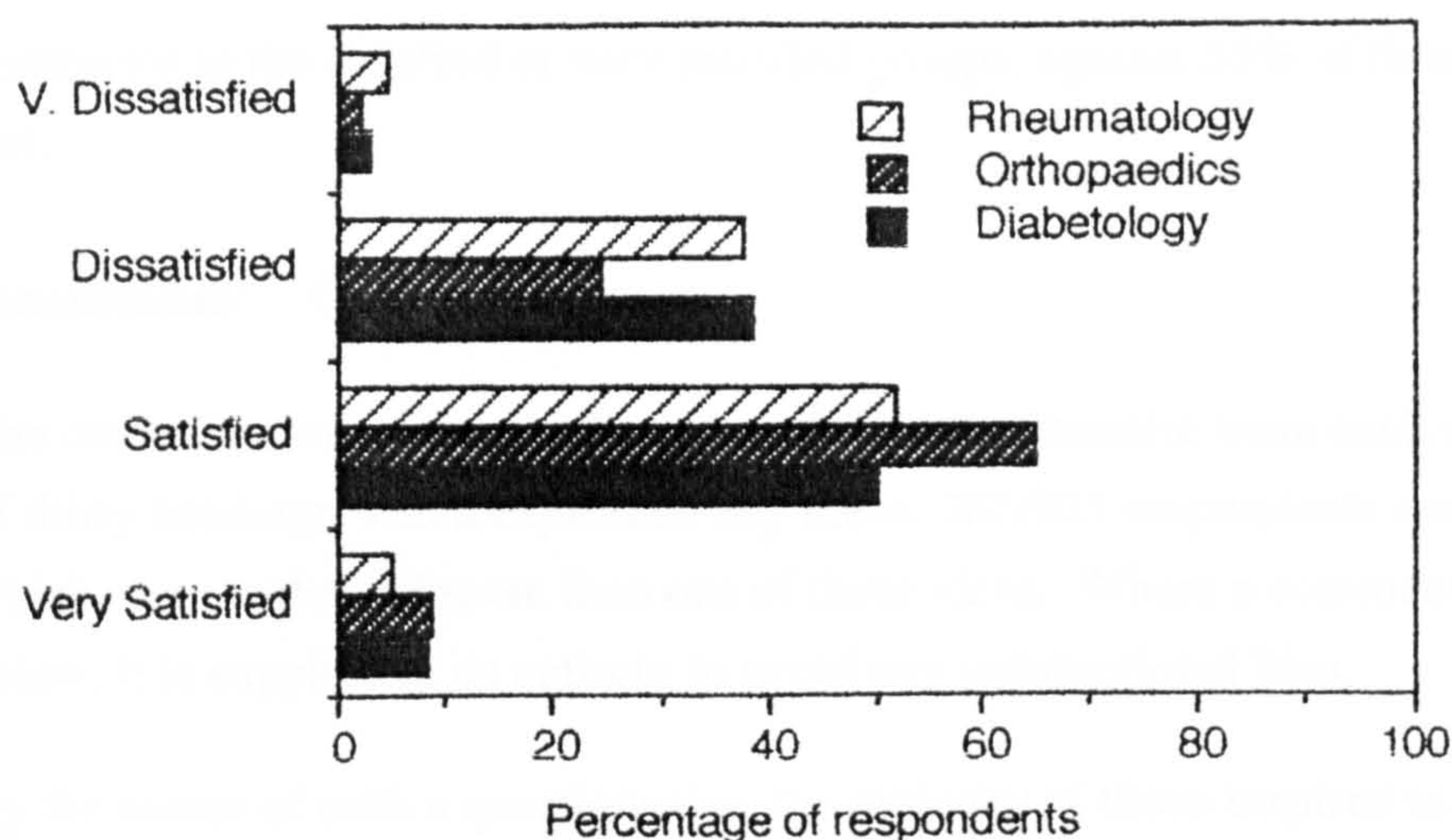


Figure 2.11. Consultants Overall Level of Satisfaction

Variation by Area

Large variations were found in the level of satisfaction with both the speed of production and suitability of footwear between the regions. Dealing first with the UK except Scotland, satisfaction with speed varies from under 30% in NThames to over 70% in the Northern region. Satisfaction with suitability is higher, from 55% in NW Thames to 90% in the Northern region.

In Scotland proportionally less consultants are satisfied with the speed of delivery, from around 20% in N Scotland and Grampian, to 60% in the more densely populated South East. Again the satisfaction with footwear once it arrives is higher.

Correlations between Results

Clinic size and satisfaction level

No correlation was found for any of the three groups with the numbers of referrals made each year, question 2, and the level of overall satisfaction expressed, question 13. Thus consultants with a larger list are not more satisfied than those with a smaller list or vice versa.

Relationship with fitter

The question was posed “are those consultants who could name their contractor, question 10, more likely to be satisfied, question 13, than those who could not”. Overall, the figures support this view, with 69% of those who could name the

contractor in the satisfied or very satisfied groups, against 55% of those who could not.

Consultants' Comments

The comments written on the last page of the questionnaire were analysed against a list of thirty headings which expressed key ideas. 285/821 respondents wrote comments which often embraced more than one of these ideas. Where a comment is repeated below, it is supplied in its entirety to avoid any unintentional bias.

By the nature of such a questionnaire, the majority of those inspired to write do so out of dissatisfaction. The comments are therefore expected to be largely concerning those areas of the system with room for improvement, which does not reflect on the majority of the service which may be functioning perfectly well. It is noted that 16 respondents wrote to describe the good system at their own centres, and that many respondents praised specific contractors for good service over years.

By far the largest numbers of citations (62) reinforced the general dissatisfaction with the speed of the service, with a further 16 comments relating to the desirability of provision of on-site capabilities, or more frequent fitters' visits, to relieve the situation. "Children are growing out of the shoes before delivery, and long waits for fitting appointments are frequent."

A large group (49) commented on the increasing use of off-the-shelf extra-depth shoes to circumvent the delays in fitting. In most cases the introduction of these 'comfort shoes' is seen as being a good thing, both for speed of service and for cost considerations:-

"We are to a large extent abandoning made-to-measure footwear in favour of the increasingly wide choice of off-the-shelf shoes which are cheaper, provided more quickly and more acceptable cosmetically. I leave it to my appliance officer to take the initial decision of off-the-shelf or made-to-measure. The CAD system outlined may improve the speed of delivery but I wonder if this will be enough in the cost-benefit analysis. "

(Rheumatologist from South East Thames)

Surgical shoes are said to have a poor fit perhaps requiring many fittings to succeed (31). It was frequently commented (38) that either the doctor or the fitter does not have sufficient training or skill to cope with the particular clinical condition, with special

reference being made to the requirements for the diabetic foot. The appliances do not meet the specifications (for the clinical condition) (9).

For some (13) the cosmesis of shoes is seen as poor; unreasonable expectations on the behalf of patients are also blamed for non-compliance by a very few (4), and the patient's viewpoint does not always concur with the prescriber's (5) :-

“Patients have unreasonable expectations and want comfort and style for bad feet. Worse still they seek surgery to allow fashionable shoes to fit. The patients are the real culprits in this whole unhappy saga.”

(Orthopaedic surgeon from West Midlands)

The patient's role is important to success. The patient's view may not be elicited or taken sufficiently into account, or the relationship between patient and fitter accorded sufficient importance (10).

The relationship between the consultant and fitter was frequently the subject of comment; many felt that a close relationship with joint clinics provides the best chance of success or could be vital (30). This link is felt to work well provided that the right person is in place (16). However there is also some support expressed for the appointment of a hospital orthotist to provide the link with the commercial contractor (15).

Although surgical shoes are thought expensive by some (18), one consultant reinforced the value of good shoes in prevention of costly surgery:-

“The problem I have is an enormous waiting list for major and minor foot surgery in all age groups. The production of a comfortable pair of outdoor walking shoes although not cheap, can preempt and avoid surgery within 4 - 5 weeks at a fraction of the cost. Frequently foot surgery fails and this creates even greater problems for the Health Service. (Foot specialist consultants should only perform the surgery in an ideal world so I am a great protagonist of footwear.) “

(Orthopaedic surgeon from North East Thames)

Free shoes may be leading to abuse of the system (18), and it was commented that a nominal charge should be made for footwear as is the case for other appliances. The

positive side of charging was expressed, in that a patient who has to pay towards the shoes is more likely to insist on acceptable fit and cosmesis, leading to improvements in the product. Abuse could be attributed to the patient who allows shoes to be made with little likelihood of subsequent usage:-

***Room for application of new materials in provision of footwear.
Frequently an unreasonable expectation for surgical footwear.
Free surgical footwear a crazy anachronism.***

(Orthopaedic surgeon from West Midlands)

The interdisciplinary clinic find frequent favour, with 24 comments that this is successfully used or preferred. The 16 respondents mentioned earlier, reporting that the system evolved at their own centre works well, did not necessarily concur with the desirability of an interdisciplinary clinic. Presumably this relates to the previously mentioned factor, in that any reasonable system works well with the 'right' people (ie personalities rather than professions). In other cases the involvement of too many people clearly fails:-

"The multiple contractors and surgical appliance firms together with the lack of inter district co-ordination and the many groups i.e. physiotherapists who think they should have a say make the present arrangements a shambles."

(Orthopaedic surgeon from West Midlands)

Thirty one comments were classified as 'contractual'. These relate mainly to the choice of contractor. In these comments were evidence of the financial pressures that are coming to bear on hospitals. In several cases, consultants report that the best contractor is also the most expensive, and that a change of contractor - often not necessarily in the footwear patients' best interest - had been initiated by the need to reduce costs. One respondent pointed out the difference between cost and cost benefit. A few comments specifically mention the need for more competition between contractors, and/or the lack of impartiality:-

"The major dissatisfaction is the lack of impartial advice. Patients referred to the Appliance Department see and are fitted by the commercial fitter available on that day, who, naturally, recommends his own firm's products. These may not always be the most appropriate in every case."

(Rheumatologist from Wales)

New materials and modern methods would be welcome (13) and our CAD/CAM initiatives received a cautious welcome from thirteen consultants. There were a small number of comments which related to each of these aspects :-

- delivery check - who should or does perform this?
- transmission of requirements from fitter to manufacturer causes problems.

Finally some comments show a general frustration with aspects of the situation:-

“There is a gap in the training of most (if not all) S.Rs. in the prescription of footwear. The standard of even simple insoles is very low - I don't think our fitters are below the general standard. The level of patient satisfaction is low. There seems to be a reluctance to use modern materials and listen to the patients requirements. Fitters are often stuck in their ways and do not like accepting suggestions from consultants who are usually younger than them. Are there no young men going into orthotics?”

(Orthopaedic surgeon from East Anglia)

“Very bad set-up. Never meet the orthotist. I cover 4x/DG hospitals, all seem to have different arrangements as does ALAC. Footwear also supplied by chiropodist workshops, & insoles could also come from other sources (OT & Physio). Even less access to other orthotics. Untrained 'secretaries' act as intermediaries as Appliance Officers to make communication even more tenuous. Ideal would be to have orthotists/OT/physio/clinical psychologist and rheumatology coordination nurse all able to attend some of the Rheumatology (or orthopaedic etc.) clinics. “

(Rheumatologist from Wales)

The above respondent makes the only mention to clinical psychologist. With the complicated arrangements tolerated in this clinic, one might wonder if the staff need the psychologists service more than the patients!

2.4 IMPLICATIONS OF THE SURVEY RESULTS

The following overall picture of footwear clinics from the consultants' viewpoint is presented

- the largest numbers of footwear are prescribed by orthopaedic surgeons to elderly patients who are slightly restricted in their activity level
- the orthopaedic surgeon has a typical case load of 20-50 referrals per annum, with all age groups likely except young adults, works closely with the fitter, and on the whole is likely to be satisfied with the result except for the speed of service
- a rheumatology consultant typically has a similar annual referral rate with slightly younger and more disabled patients, although few children, works closely with the fitter, is even less satisfied than his orthopaedic colleague with the speed of the service, and less content with the suitability of the footwear
- a diabetic consultant has a lower annual referral rate with similar activity level, is less likely to work closely with the fitter and more likely to use the chiropody or therapy services to supply footwear, and is also less satisfied than his/her orthopaedic colleague with the speed of the service and suitability of the footwear

With regard to the route for supply, the consultants responded that

- the single most apparent need is for improved speed of delivery
- the system of operation varies widely from clinic to clinic, and although the most common route is for the consultant to liaise directly with the fitter, other clinical professions (medical colleagues, chiropodists, physiotherapists, occupational therapists, nurses) and the appliance officer may be involved in the initial consultation, technical specification and/or checking procedures
- success is claimed for both the system of close liaison between consultant and fitter, and a multidisciplinary clinic approach, but both are dependent on getting the right people with the right training and both break down into disrespect/chaos
- chiropodists play an important role in footwear supply for the diabetic patient
- although physiotherapists and occupational therapists may suggest the need for footwear, consultants do not report their major involvement in the subsequent supply

- there may be difference in the levels of satisfaction across the country.
- there is certainly room for improvement in the fit and suitability of the footwear for particular conditions
- the use of stock orthopaedic shoes (extra-depth shoes) is finding wide support

2.5 DISCUSSION

The survey has provided a wealth of high-quality data from which analysis has yielded a number of statistically significant results and other observations.

Most importantly for the future of our CAD project is the perceived need for reduction in the delivery time for footwear. With traditional craft methods, this cannot be realistically improved to any large degree. Even if the factory meets the suggested six-weeks maximum turn-around time from receipt of cast/measures to dispatch for trial fitting, the overall supply time is probably too long by clinical criteria. Neither are these clinical demands without foundation: preventable diabetic foot ulcers are occurring in the interim which can lead to costly in-patient nursing requirements or to surgery; the remaining life of the shoe for children with growing feet implies more frequent supply than necessary, with all its attendant cost and inconvenience; and patients' mobility and lifestyle may be compromised for long periods of time. Only by a change in technology can this situation hope to be resolved at affordable cost.

Fit, suitability and speed of delivery of footwear are inextricably linked. Poor fit or unsuitable specification lead to multiple fittings and slow delivery. These problems must be linked within the CAD/CAM solution.

The improved training requested by a large number of respondents could occur on a more objective and scientific base within the more quantitative framework of CAD/CAM.

The reported interest and growing awareness of stock orthopaedic shoes may influence the pattern of prescription in future. The use of extra-depth shoes with a thicker resilient insert was primarily utilised for accommodation of the sensitive foot. Perhaps with a shaped semi-rigid or rigid insert the usage for orthopaedic corrections will increase. The figures quoted in the Introduction Chapter suggest that already an appreciable part of the budget may be spent on shoe inserts. It is expected that the usage of stock shoes will increase in future, with the combination of off-the-shelf shoe and customised shoe insert replacing some of the market for bespoke shoes. This market is at present limited somewhat by the need to specify a size for a catalogue style, in the absence of large stocks in the clinic. The survey therefore suggests that the design and fitting of semi-bespoke shoes is an important area for future consideration. It also supports the development of insert design as a module which can be used either as a stand-alone system or as part of the integrated shoe system.

As expected, the survey confirms the major role of the contractor's fitters in technical specification of the footwear, and it is clear that both the fitter and the consultant will need to be persuaded by the potential of CAD in order for the system to gain acceptance. Chiropodist should also be included in the education process for the diabetic foot in particular. It may be noted that chiropodist have traditionally supplied shoe inserts without need for a consultant's prescription, and may take a major role in the supply of these items in the community. Despite some suggestions that therapists should be included in footwear supply training, the consultants do not perceive this group to play a significant role in supply, other than perhaps in identification of need.

2.6 CONCLUSION

With the advent of clinical accounting in NHS hospitals, consultants may in future be more directly responsible for the effective use of the budget for their clinical area. Their requirements for the footwear supply will become even more important in determining the contractor and type of footwear. The consultants' clearly expressed desire for a faster service is not without clinical foundation. Patients could be spared treatment of ulcers, corrective surgery or amputation if correctly-fitting footwear arrived in time. Children would have a longer period before outgrowing the footwear. The financial implications to the consultants' budget should be apparent.

Some concern has been expressed that for economic reasons the contractor has been changed without clinical reason. It can be perhaps anticipated that the criterion will tend towards cost-benefit rather than cost alone in future, where hospitals are managed on more commercial lines.

It has been suggested that patients should pay towards their footwear. This view appears in step with current political thinking, and would probably result in the patient demanding a higher standard with less subsequent rejection of footwear. Whether it would also produce a reduced demand is debatable; if the majority of the prescriptions at present are warranted, then presumably the demand will not fall substantially provided that the footwear is acceptable. However the consumer organisations have expressed strong opposition to this approach (DLF meeting, November 1991).

Any future development in footwear supply should heed both the requirements of the consultants outlined in this report and those of the patients solicited in earlier surveys. The latter may put more emphasis on cosmetic factors. It is noted that both the increases in speed of production, and improved cosmesis are likely outcomes of introduction of computer-aided design and manufacture systems.

A summary of the results of this survey have been published (Lord & Foulston 1989).

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CHAPTER 3. FOOT PRESSURE MEASUREMENT

3.1 BACKGROUND

Methodology of Pressure Measurement

The distribution of load under the foot has long been studied for its academic relevance to biomechanics of the lower limb. Very many different pressure measurement techniques have evolved over a long period, based on many different transduction principles. These were reviewed by the author (Lord 1981) where a basic classification into printing methods, visualisation techniques, force-plates & load cells, and insoles & pressure pads methods was made. Different methods of measurement and advances on the more established methods have continued to be reported. An update was included in a review of clinical applications (Lord et al, 1986). Alexander et al (1990) have extended this review more recently, with a concentration on those techniques suited to dynamic measurement during walking. Significant developments since 1986 are noted below under the author's original classification.

Printing methods have been updated with the development of Fuji Prescale Film, whose use is reported by Ralphs et al (1989). This pressure sensitive film changes colour permanently with the application of pressure, and hence records the maximum pressure applied during its exposure. The material has existed for some time, but its pressure range has now been adjusted to a level suitable for plantar pressure work. The quantitative evaluation depends on comparison of the film with a colour standard, all shades of red for this material, which has a subjective element. Also it was determined that the material must be exposed to the pressure for at least two minutes to develop its final shade: this appears a serious limitation. Continued use of pressure-sensitive film containing microcapsules of dye is reported in an assessment of the pressure on the points of ballet dancers (Tuckman et al, 1992): these authors report favourably on the accuracy and pressure range (500 to 1900 kPa for super-low grade) of this material, although the range would appear to be rather high for a more routine plantar-pressure applications.

A novel visualisation method based on generation of Shadow Moiré (Asundi, 1986) can also provide a quantitative result by off-line analysis of the fringes (Fok, 1988). This has serious disadvantages, however, in both the analysis time inherent in Moiré methods and because of the limitation to static conditions of this particular apparatus. Rhodes et al (1988) have extended the photo-elastic method previously reported by

Arcan and Brull (1976), and later developed by Cavanagh and Ae(1980), to overcome the poor resolution of the previous device: now using a continuous flat sheet of photoelastic plastic for the transducer and an overlying indenter with grooves at 3 mm spacing, the system is claimed to provide high spatial resolution and good dynamic results through its PC-based analysis system.

The most important advances, in terms of clinically-useful devices, have been made in the technology in the forceplate and insert classes, with systems now offering a flat mat with a fine matrix of individual load cells: furthermore, some systems can provide a flexible insole version of the matrix, which allow for the distribution of in-shoe pressure to be measured in a continuous and dynamic fashion previously unobtainable. These insert devices are particularly exciting since, through them, it now becomes possible to contemplate a more quantitative approach to the use of pressure distribution information in shoe insert design.

In the commercial arena, the EMED¹ system of a flat mat and inserts uses capacitive transducers, whereas the F-Scan² flat mat & insole, and the Musgrave Footprint ³, are all based on force-sensitive resistor (FSR) technology. All can deliver a matrix of cells spaced at approximately 5 mm centres, which cover the majority of the surface of the mat or insole. In general, the capacitive-based system is accurate, repeatable but very expensive. FSR technology produces a cheaper basic transduction material .However the threshold of this system must be relatively high due to an inherent property of the material. The high resistance of each cell at no-load has an extremely variable value, which reduces and comes rapidly closer to the nominal calibration curve as load is applied. It is therefore necessary to apply a threshold value below which the readings are highly inaccurate. FSR technology also suffers from heat sensitivity. Its advantages over the capacitive system are predominantly cost, plus the added benefit that the insole can be trimmed to size.

The commercial insert systems both necessitate the subject to be tethered by a lead to the computer-interface, and record a limited number of steps in a short walk. To provide for a long-term recording, a portable system has been developed (Wertsch et al, 1992). The 14 sensors in the insole are made from a conductive polymer, and the battery-powered system can collect samples over a period of 2 hours. The reduced number of elements , 14 compared to a maximum of 960 in the F-scan insole system

¹ Novel gmbh, Beichstrasse 8, 800 Munchen 40, Germany

² Tekscan Inc, 4th Floor 451 D Street Boston, Mass.02210 USA

³ Preston Communications, New Ross, Dinbren Road, Llangollen, Clwyd LL20 9TF, UK.

for example, is a major factor in the ability to record over long periods; it is however a disadvantage in terms of spatial resolution.

Normative Studies and Clinical Applications

Clinical applications of foot pressure measurement were reviewed by the author at the start of this work (Lord et al, 1986). There have been considerable developments over the period of this study, especially linked to the development of dynamic pedobarographic analysis and insole pressure-measuring devices.

Normative studies

A large survey of 107 asymptomatic feet has provided good normative data on barefoot standing pressure distribution (Cavanagh et al , 1987). Mean peak pressures were established for arbitrary regions of the medial and lateral heel & midfoot, and the medial, central and lateral regions under the metatarsal heads and the toes (ie. the peak pressure occurring on a single cell within each region, measured on a mat with 1 cm x 1 cm spatial resolution). The results show that the highest mean pressures are under the heel area, with very little pressure under the toes

	Medial	Central	Lateral
Toes	20.6	8.7	16.1
Forefoot	38.4	51.8	53.4
Midfoot	19.2	n/a	27.8
Heel	138.9	n/a	132.6

Table 3.1 Pressures (kPa) under the toes in standing given by Cavanagh et al, 1987.

These values are discussed with regards to traditional theories of the function of the foot. The presence of a transverse metatarsal arch is not supported by the findings. Integrating pressure over areas, it is possible to determine the load in each region. The heel carried a surprisingly high 60%, the midfoot 8% and the forefoot 28% of the load, with toes only minimally involved. These results are not dissimilar to those previously reported although a direct comparison is not possible due to different analysis techniques, eg. Betts et al (1980) who reported that the forefoot 'half' of the foot carries 43% of the load. No significant relationship was found between bodyweight and the maximum pressures.

In a comparison of pressure distribution during gait, the feet of 15 very young children and 111 (asymptomatic) adults were measured by Hennig and Rosenbaum (1991). The infant foot skeleton differs from the adult, and the major structural changes of

cartilage to bone are not complete until the age of 6. Differences might therefore be expected in the pressure patterns under the children's feet (age 14 to 32 months). This report uses a similar analysis of regions to that of Cavanagh reported above, citing the peak pressures occurring under the medial and lateral heel, midfoot, 1st, 3rd and 5th metatarsal heads, and the hallux. The study also recognises the importance of the duration as well as the magnitude of the high pressures and, in a terminology which is now frequently used, also determines maximum impulse values ie. the integration of the *force* vs. time for one walking cycle. The EMED system was used, providing a resolution of 2 sensors per cm². Results from this study show peak pressures for adults to be greatest in the forefoot and toe area (hallux at 416 kPa, 1st, 3rd, 5th metatarsal heads at 314 / 380 / 216 kPa, and the medial & lateral heel at 312 / 277 kPa respectively). These results are compatible with the established biomechanical theory, where the forefoot and toes provide the support and forward propulsion at the push-off phase of gait, and are therefore expected to be proportionately more highly loaded than in standing. The children showed a similar pressure pattern with an overall reduction in the absolute values of a factor of approximately 3, except in the midfoot area where the two groups has a similarly low pressure of 41 kPa (children) and 59 kPa (adults). The impulse patterns show a more even overall loading of the infant foot compared to the adult.

The Normal Foot in High-Heeled Shoes

There is very little published on the effect of shoes on foot pressure, primarily due to the very recent emergence of insole measurement techniques. However, through an ingenious experimental technique involving fenestration of the sole of the shoe, Snow et al (1992) have recorded the effect of wearing high-heeled shoes. Low, medium and high-heeled shoes each were adapted with a window in the forefoot to enable recording under the metatarsal head and the hallux. Normal subjects then walked in these shoes over a pedobarographic plate. As might be expected, the maximum peak pressures in the forefoot all increased with increasing heel height: for example, under the 1st metatarsal head, the pressure rose approximately linearly from 230 kPa barefoot to 450 kPa in a heel of quoted height 8.26 cm. The support times were significantly less for the barefoot condition than any of the shod conditions, but there were no significant differences recorded for any of the shod conditions. Some alteration in the pressure distribution across the forefoot was noted, with increased loading medially: it is suggested that the shape of the shoe toe box, which restricts the width of the forefoot, might be a cause.

Foot Pressure with Diabetes and Hanssen's Disease

The foot complications of diabetes can lead to plantar ulceration, predominantly of neuropathic origin. The neuropathic ulcer occurs in an otherwise healthy and viable foot and it is thought that there is a strong causative link with mechanical stress. For this reason, many authors have previously described the pressure pattern under the diabetic neuropathic foot. In work reviewed in Lord et al (1986), the dominant characteristic of the pressure pattern is the presence of local regions of abnormally high pressure usually situated in the forefoot. The link between the sites of ulceration and these high pressure sites is well-established (Stokes et al 1974; Ctercteko et al 1981; Boulton et al 1983 & 1985).

Hanssen's disease can present similar foot problems to diabetic neuropathy: the foot is insensate and tends to form plantar ulcers which can be healed with appropriate footwear. Mothiram-Patil and Srinivasan (1987) used a pedobarograph to examine the feet of leprotic patients, carefully comparing the patient group to a group of normal subjects measured on the same apparatus to overcome difficulties with absolute calibration. Whereas the peak pressures of the normal group did not exceed 350 kPa at any part of the sole, the scarred sites of healed ulcers correspond to discrete sites of very high pressure, two to three times that of normal feet. This is in line with the findings for the diabetic ulcerated foot. The authors propose the use of the barograph to assist in the design of shaped insoles to redistribute the pressures under scarred tissues to a more normal level.

Foot Pressure and Rheumatoid Arthritis

The distribution of pressure under the feet of the rheumatoid patient reflects the various clinical observations of this condition (reviewed in Lord et al, 1986). The migration of the fatty padding from under the metatarsal heads leads to very high pressure peaks under discrete heads (Minns & Craxford, 1984; Soames & Carter 1981): the clawed toes may be dysfunctional and therefore toe pressure is reduced or absent: the flat-foot gait is reflected in an absence of the medial roll of load at push-off, and hence the forefoot loading is more lateral (Minns & Craxford, 1985), and the impulse analysis shows a decrease in forefoot function (Soames et al, 1982).

Since that review, this has been an active area of work between researchers at Sheffield and Manchester, particularly into the assessment of forefoot arthroplasty. A prospective study of 35 patients about to undergo surgery for pain relief was made (Betts et al, 1988). The metatarsal heads were removed in this operation. In the preoperative group, 70% of the patients had abnormally high pressure in walking,

mostly under the 1st, 2nd and 3rd metatarsal heads, and occasionally under the 5th. Pressures as high as 20 kg/cm² (2000 kPa) are reported using a pedobarograph technique. Postoperatively, the high pressure was removed from the central metatarsal region in most cases, but only a few reductions were found under the 1st and 5th region. By making both static and dynamic recordings, this study brings out the interesting factor that although the number of sites of high pressure were the same in both cases, the locations of the sites were not. Only two thirds of the sites overlapped, leaving one third that were only identified on standing and not walking, and one third which were identified on walking and not standing. The results support the lack of toe function with little evidence of toe pressure.

Technical Limitations of the Current Methodologies

To employ pressure distribution in the design of shoe inserts requires a level of understanding of the technical limitations of the measuring devices. These can, for example, give very misleading results on which design decisions may be erroneously based. It also requires an understanding of the requirements for redistribution of pressure by the inserts. As an example, it is often the case that the design is intended to reduce some peak of pressure to a tolerable level, either by spreading it locally in the case of cushioning or by shifting it to another part of the foot such as the midfoot. In this case, it is desirable to know what level of pressure can be tolerated.

This chapter describes two fundamental characteristics of measurement systems which have previously not been thoroughly considered, namely spatial resolution and threshold. An evaluation of their significance to the accuracy and interpretation of pressure maps is made. Then three case studies follow, where foot pressure measurement has been carefully employed in the first case to evaluate the effect of callus debridement on local peaks of pressure, secondly to determine the location of high pressure, and thirdly to evaluate the pressure distribution afforded by a moulded insert design. Finally, a discussion of plantar shear stresses is added, with a description of the work initiated in this area.

Much of the experimental work in this chapter is based on the device known as a pedobarograph [Betts & Duckworth, 1978; Chodera and Lord, 1979]. The original invention was reported by Chodera reported in his Czech Doctorate thesis: the author assisted Chodera in the early development of the pedobarograph at UCL's Bioengineering Centre (Lord & Chodera, 1978; Lord, 1979; Lord & Smith, 1982). This device is now widely available and used in research and clinical settings.

A comparison of this method has been made (Hughes et al 1987) with an inked rubber printing mat of Harris & Beath design, a matrix force-plate (Dynapod: Dhanendran et al 1978). From normal subjects, this study demonstrated that the different characteristics of spatial resolution, threshold and dynamic response acted to produce differing results for apparent peak pressures. Under the great toe, the Dynapod recorded higher values than the pedobarograph, which is attributed to its faster response. It is assumed that the pedobarograph attenuated the fast peaks. Under the lateral toes the pedobarograph recorded higher pressures, which is attributed to its lower threshold and better spatial resolution. The Dynapod cells could fail to reach the minimum force needed to trigger in these low pressure marginal areas. Practical consideration in the use of the pedobarograph have been explored by Homes et al (1991). These authors used normal subjects to assess the influence of the number and timing of trials on dynamic pressures, concluding that three trials on 1 day should reduce the estimates of error sufficiently for clinical and research purposes, ie. bring them within the limits of accuracy of the machine.

The remaining work is based on the F-Scan insole device which was described above, for which the author contributed to pre-commercial release trials with the development company. This device has now been released for general sale.

Magnitudes of Pressure under the Foot

As a general basis for the following work, it is pertinent to consider the magnitudes of pressure found under the foot. Taking a rough estimate of a fairly average adult female of weight 600 N, the area of the feet in contact with the floor in normal standing has been estimated by a simple imprint method as 200 cm². Thus the average pressure under the feet is approximately 30 kPa. The mean peak pressure found under asymptomatic feet in stance was 140 kPa (SD 30 kPa, n=107) (Cavanagh et al 1987) whereas in barefoot gait peak pressures of 416 kPa (SD=187 kPa, n=111) are quoted (Hennig & Rosenbaum, 1991). Pathological conditions such as diabetic neuropathy can lead to pressures reaching the level of 2,000 to 3,000 kPa in barefoot gait.

Thus it must be noted that the peak pressures experienced under the feet are considerably higher than the average pressure. This implies that the pressure distribution is uneven with

- small areas of high pressure
- large areas of very low pressure.

This factor is critical in much of the following discussion.

3.2 DETERMINATION OF SPATIAL RESOLUTION EFFECTS

Introduction

Peaks of high pressure under the feet are frequently accorded clinical attention because of their potential to cause mechanical damage. Problems have arisen in obtaining comparability of results of peak pressure measurements between various research groups using different equipment and techniques. It has been suggested that the lack of consistency may be largely due to technical factors in the different pressure measuring systems (Hughes et al, 1987). Spatial resolution is one of the technical factors which contribute to this problem. Of the very many different techniques for measurement of foot loading, the majority have low spatial resolution, including most of the flat-plate devices useful for barefoot measurements. This is also so for the later systems for in-shoe pressure distribution measurement. These consist of a matrix of load sensing elements on a flexible insole, eg. the EMED insole, the F-Scan insole and the capacitive-element system described by Hennig and Rosenbaum (1991). At present the elements are all approximately 5 mm by 5 mm or larger. Because the pressure recorded is an average value over the area of each cell, and not a true continuous distribution, it is possible the true peaks in the pressure profile are not measured accurately. The averaging can be regarded as a form of spatial filtering which will reduce high frequency content.

In order to study the requirements and effects of spatial resolution, it is necessary to use a measuring device with good resolution such as the pedobarograph as a standard. In this present study, pedobarographic studies are used to evaluate the spatial characteristic of plantar pressure profiles in barefoot standing, and to evaluate the requirements for spatial resolution for accurate representation of pressure profiles under diabetic neuropathic feet (which are known to have high peaks of pressure occurring). Because the pedobarograph is a difficult instrument from which to obtain repeatable and calibrated results, special attention is paid to this aspect of the data capture.

Method

Equipment

The pedobarograph used in the experiments comprises a pedestal with a top edge-lit plate of white glass covered by a textured foil, an angled mirror and a CCTV camera. This flat-plate optical system provides a quasi-continuous pressure distribution mapped as an analogous light intensity image on the underside of the plate. The camera picks this up as a live video image, which is continuously displayed on a black-and-white video monitor for reference. A commercial pedobaroscope is available following this design ⁴.

Observations over a long experience with pedobarographs have suggested that barefoot standing yields pressure distribution patterns which are reproducible, characteristic and relatively invariant with posture on a single machine (Lord,1981). Variability observed between machines is therefore a characteristic of the transducer, the video camera used to pick-up the light pattern, and/or sensitivity of the analysis system itself. The first of these possibilities is the most probable and equally the most difficult to address with existing systems.

The most critical factor in the transducer is the foil placed over the glass plate. The choice of a pedobarograph foil depends on the application, as none of those previously tested by various groups at Roehampton, Strathclyde or Sheffield have proved ideal with respect to all the desirable characteristics, ie. linearity, thermal stability, time stability, dynamic response or plastic deformation. The moulded rubber 'baromat' supplied by John Drew Ltd. provides a transducer which is stable in time, relatively heat insensitive, and has an appropriate range for static work (0 to 1500 kPa). Its pressure/intensity curve is however non-linear and, because of its thickness, it introduces some spatial filtering, hysteresis and dynamic lags. The surface texturing is also coarse and this generates localised 'noise' in the intensity image. In this study photographic paper (Ilfospeed pearl finish) was employed as suggested by Franks and Betts,1988. This presents a hard surface under foot, and would not result in the spatial smoothing which might occur when using a thicker foil such as a closed-cell foam.

A special interactive analysis system has been developed. This allows for graphical inspection of pressure profiles in selected areas, and is also used in both spatial and pressure calibration. The programme runs on a desktop computer giving immediate inspection.

⁴ John Drew Ltd., 433 Uxbridge Road, London W5 3NT, UK

Analysis system

A single frame of the video image from the pedobarograph camera is captured via a Neotech frame grabber (resolution 768 by 512 at 256 grey levels) directly into an Apple Macintosh computer (Macplus 1/20). The captured images are stored as standard TIFF (Tagged Image File Format, Aldus Corporation) files. The file format consists of a header with a series of 'tags' which each defines the parameter immediately following (eg image width, filename, number of grey levels, starting location for the intensity data etc.). The intensity data then follows in an uninterrupted stream, scanning from the top left corner to the bottom right. The intensity data is read in as one byte per pixel at a resolution of 256 grey levels.

This application has a main working window in which the captured frame is displayed, figure 3.1. Since the graphics monitor available for this work was a one-bit black & white (no greyscale capability), a 'dithering' algorithm is used to give a simulation of greyscale by variation in pixel density. The Floyd-Steinberg algorithm suggested in Newman & Sproull (1987, p226) has been implemented in a left-to-right top-to-bottom sequence. The relationship between scanned and monitor pixels is kept at one-to-one, with the result that every pixel in the image array can be pointed to individually with the mouse-driven cursor, and the image can be scrolled to view all parts. In an information window alongside, the intensity and the location of the pixel directly under the cursor are continuously updated. Units can be toggled between measured image intensity or pressure, and pixels or millimetres. If a circular 'arena' is selected from a menu and dragged to place over an area of interest, then either the pressure profile at indicated diameters of the circle, or the average/maximum/minimum pressures inside the arena can be displayed in the information window. A tape measure graphics tool is provided to record the distance between any two points; a rubber-banded line is stretched between two features of interest to obtain the distance, and the pressure profile along this 'tape' can be viewed and saved to disk.

The programme has been written in Lightspeed Pascal (later renamed Think Pascal), conforming to the usual Apple menu-driven interface protocols. A listing of the modules, procedures, menus and programme flow charts is included in Appendix II.

Calibration

As a pre-cursor to pressure calibration, the general features of the device were explored with the interactive facilities. From previous experience with attempts to calibrate pedobarographs, it was known that the application of a deadweight via a hard flat surface onto the pedobarograph foil would not produce an even pressure distribution, figure 3.1. It was therefore proposed to average the intensity over the area of the image, and to equate the averaged intensity output to the average pressure applied. A circular 'arena' or area of interest is a feature of the analysis programme which can be used for this purpose. This procedure was first investigated.

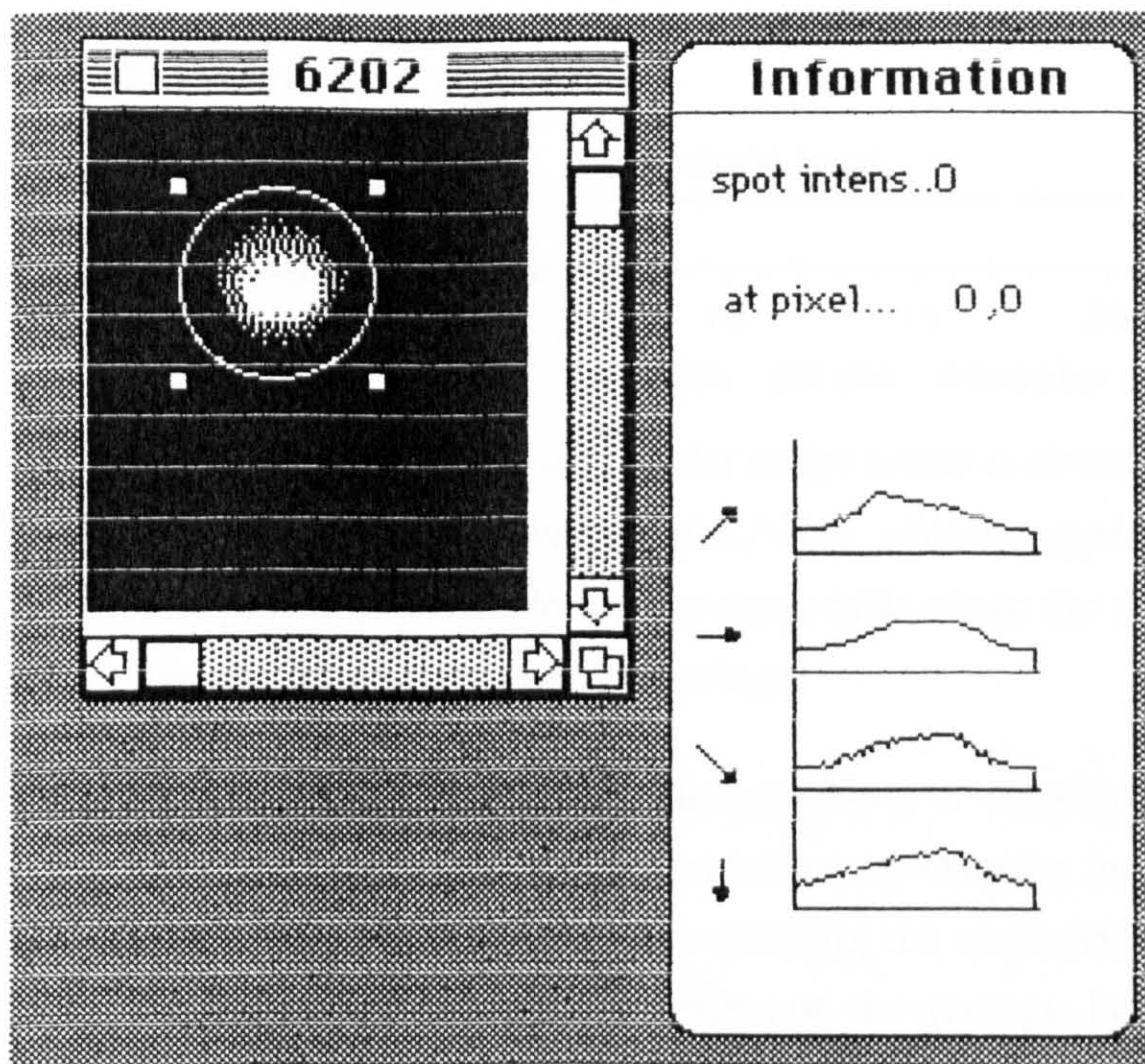


Figure 3.1 Example of a deadweight load onto a flat circular indenter produces variation in intensity across the resulting image.

A known load was then applied by adding dead-weights to a flat circular indenter with an area of 100 mm². A frame was captured and inspected subsequently. The arena could be dragged directly over the image of the indenter. Starting with the camera aperture set to maximise the range without resulting in high-level saturation, as used in clinical practice, the background intensity is approximately 100 units out of the full scale of 255 units..Using the 'spot intensity' function, a central working area for the plate of 300 mm by 300 mm was identified where variation in background intensity was less than 5 units

Profiles of the pressure under the indenter reveal a far from flat contour, figure 3.2. This substantiates the need to use some form of integrating technique in order to perform a calibration.

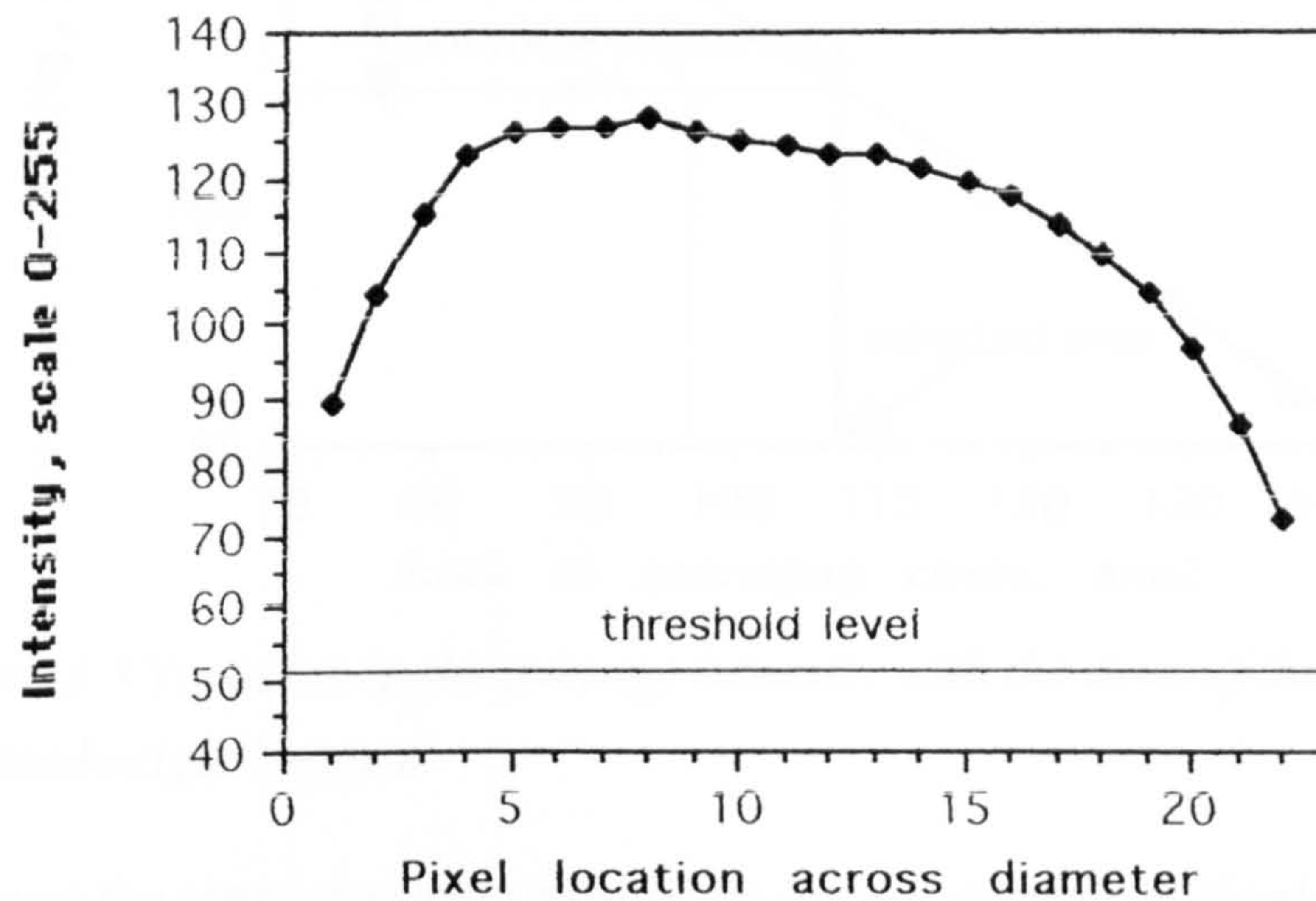


Figure 3.2 Pressure profile across the image under a circular flat-faced indenter of area 100 mm^2 with a deadweight of 4.7 kg showing typical variation across the circle. The plot is obtained by saving the profile along the stretched tape, then displaying the data in a graphing package.

The average intensity obtained in this procedure is sensitive to both the size of the circle chosen and to its exact location with respect to the indenter image. Two experiments have been performed to quantify the sensitivity. In the first, the area of the circle was varied to investigate the effect on the average, keeping its centre stationary; in the second, the central location of a circle was moved systematically with respect to the image, keeping its area constant.

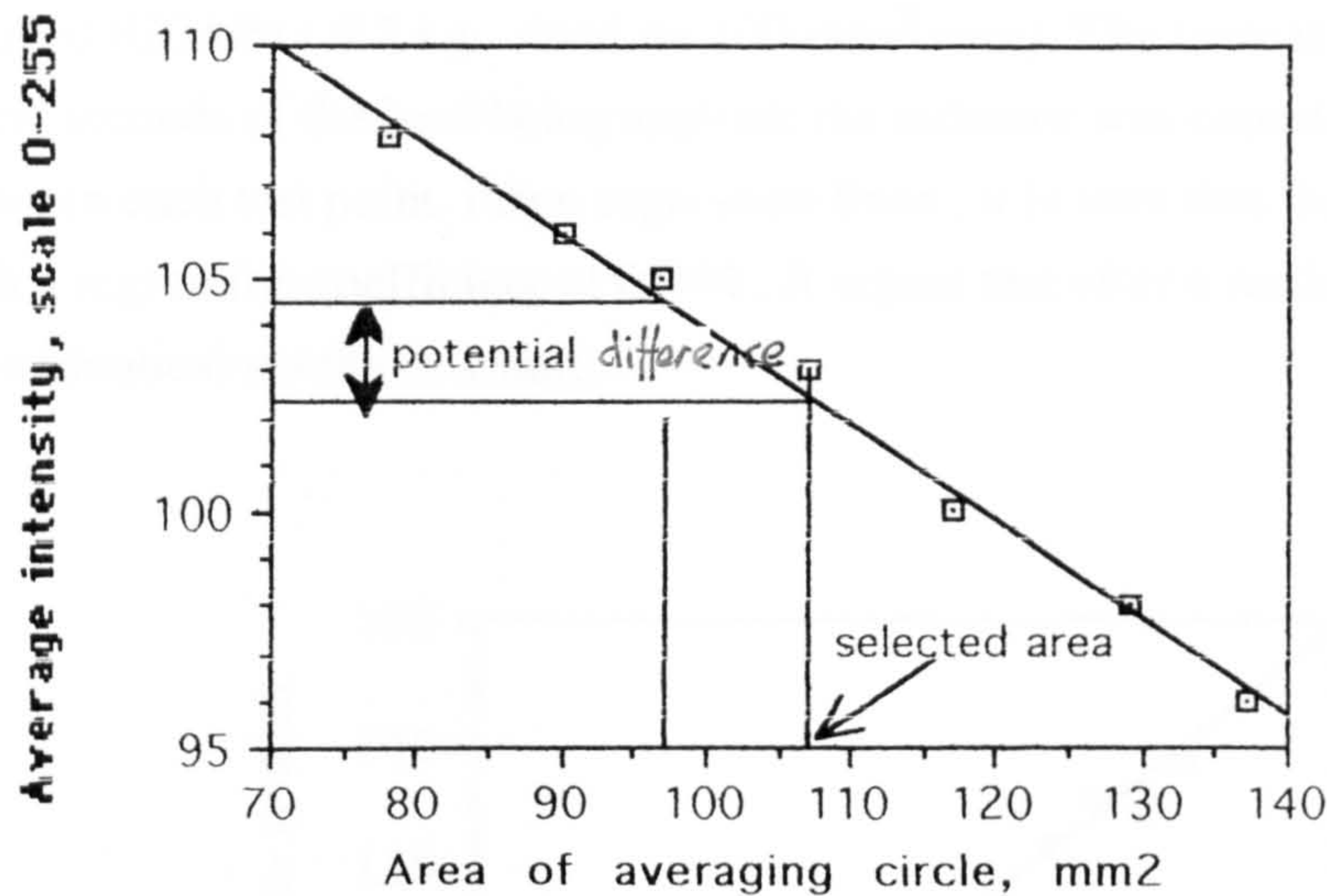


Figure 3.3 Variation in the average intensity with the area of the circle (centred over the deadweight image).

Because the arena diameter must be an integer number of pixels, it is not possible to select an arena area of exactly 100 mm^2 . With the given spatial calibration, a diameter of 21 pixels results in an area of 107 mm^2 . A plot of average intensity vs arena area is shown in figure 3.3 at one mid-range load. This shows that the *potential difference maximum* introduced by selecting the area slightly above the true value, as opposed to the next available one below, is of the order of 2.5 units in this case with a signal level of 50 units above threshold. When the averaging arena is centred visually over the indenter image, the average intensity is 103 units; moving the arena by ± 1 pixel in either vertical or horizontal directions produced a maximum variation of 4 units.

A calibration plot is presented in figure 3.4, using an arena area of 107 mm^2 , load range 0-820 kPa (8.2 kg load on 100 mm^2 area). The frames were captured within a few seconds of the load being applied: the indenter was completely offloaded between each test point. From regression lines, it is seen that the relationship is linear with a regression coefficient of 0.994. A repeat test after a resting period of 1 minute gave identical results (± 1 unit)

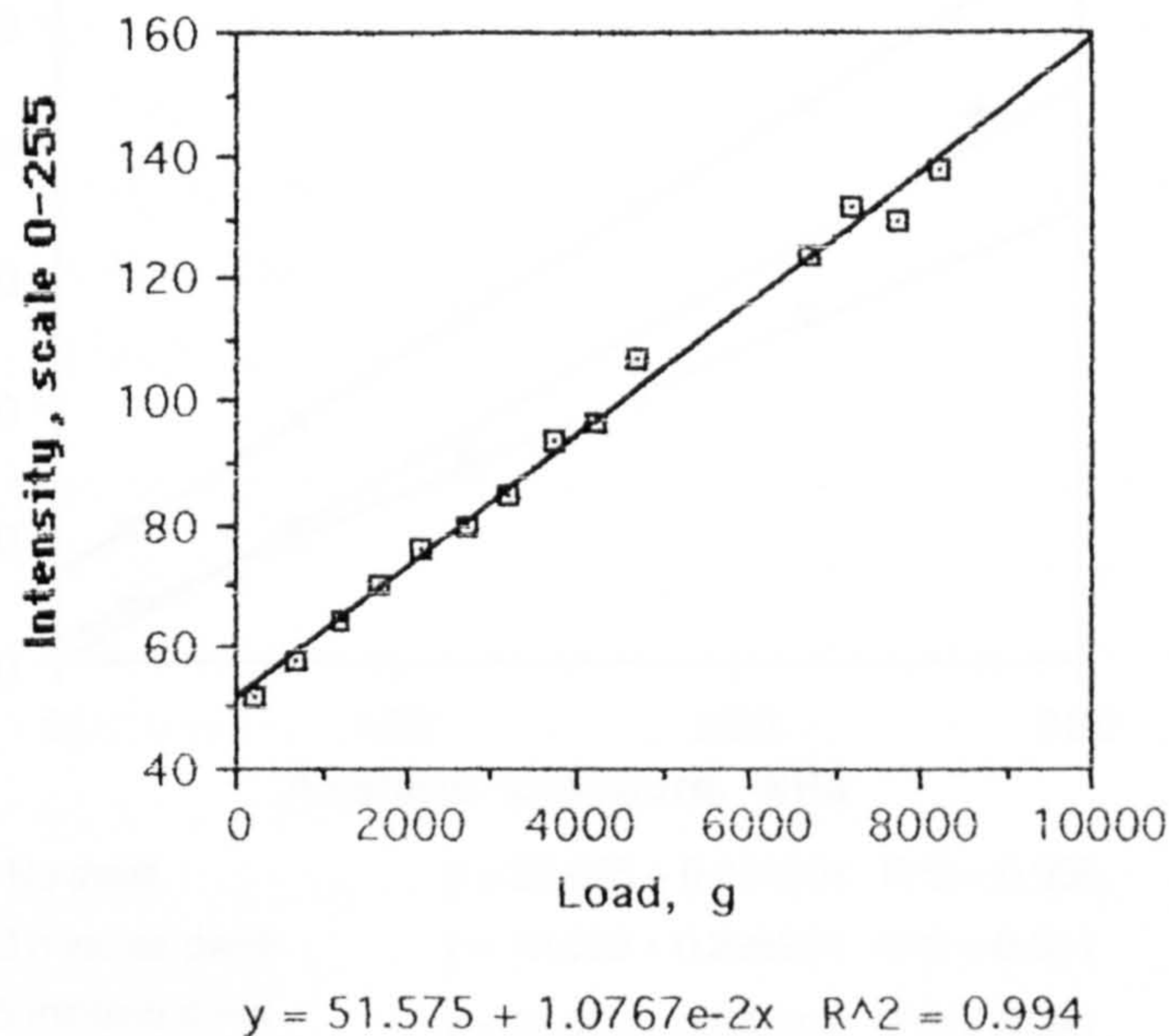


Figure 3.4. Intensity/load calibration for unfixed photographic paper, where the load is applied to a 100 mm^2 area circular indenter, and the resultant intensity is measured averaged over a nominal 100 mm^2 circular arena centred over the indenter image.

A series of frames was captured for successively increasing loads with a dwell period at each loading level. Each load was applied for 3 minutes before frame capture, and the calibrator was off-loaded for 1 minute between each load to allow recovery. At the end, a rapid test was repeated after 1 minute to confirm recovery. The entire sequence was then repeated but with a 6 minute dwell before frame capture. The rapid loading test was immediately repeated to evaluate recovery.

The load dwell was chosen at 3 minutes and at 6 minutes when creep should be completed. The tests demonstrated that the creep is proportional to the load, figure 3.5b. The maximum effect is to increase the gain of the calibration curve from 0.224 to 0.332 for a dwell of 6 minutes and also to shift the effective threshold. At a pressure of 220 kPa, the increase caused by a 6 minute dwell is 10 units over the

signal level of 50 units, or again a 20% increase. Recovery was tested by repeating the fast calibration test one minute after a dwell test. After the 3 minutes dwell test, recovery was then complete, but not after the prolonged 6 minute dwell. It is concluded that recordings should be made within the first 30 s after loading to keep the creep error below 5%. Furthermore several minutes of recovery should be allowed between successive loadings.

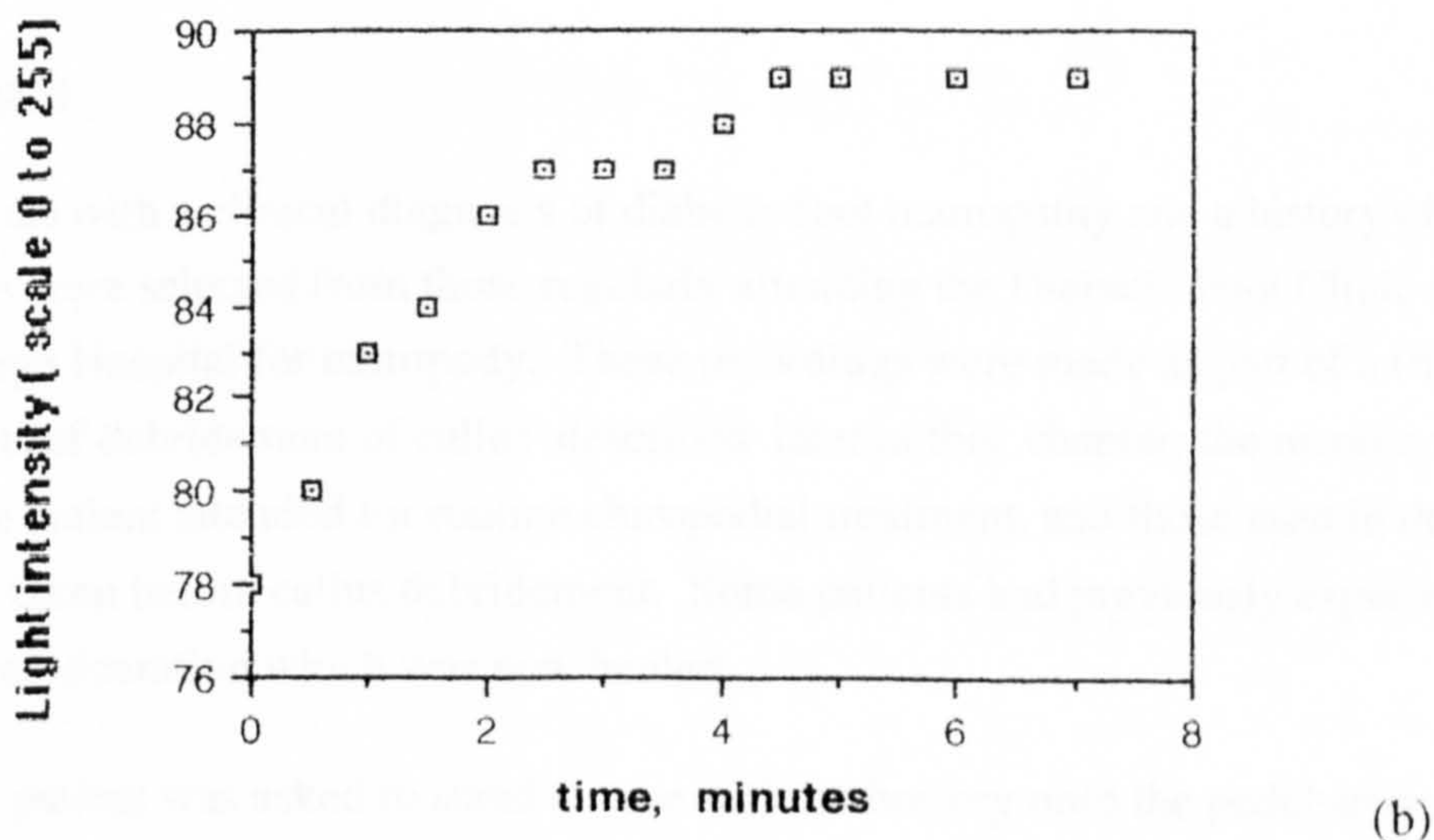
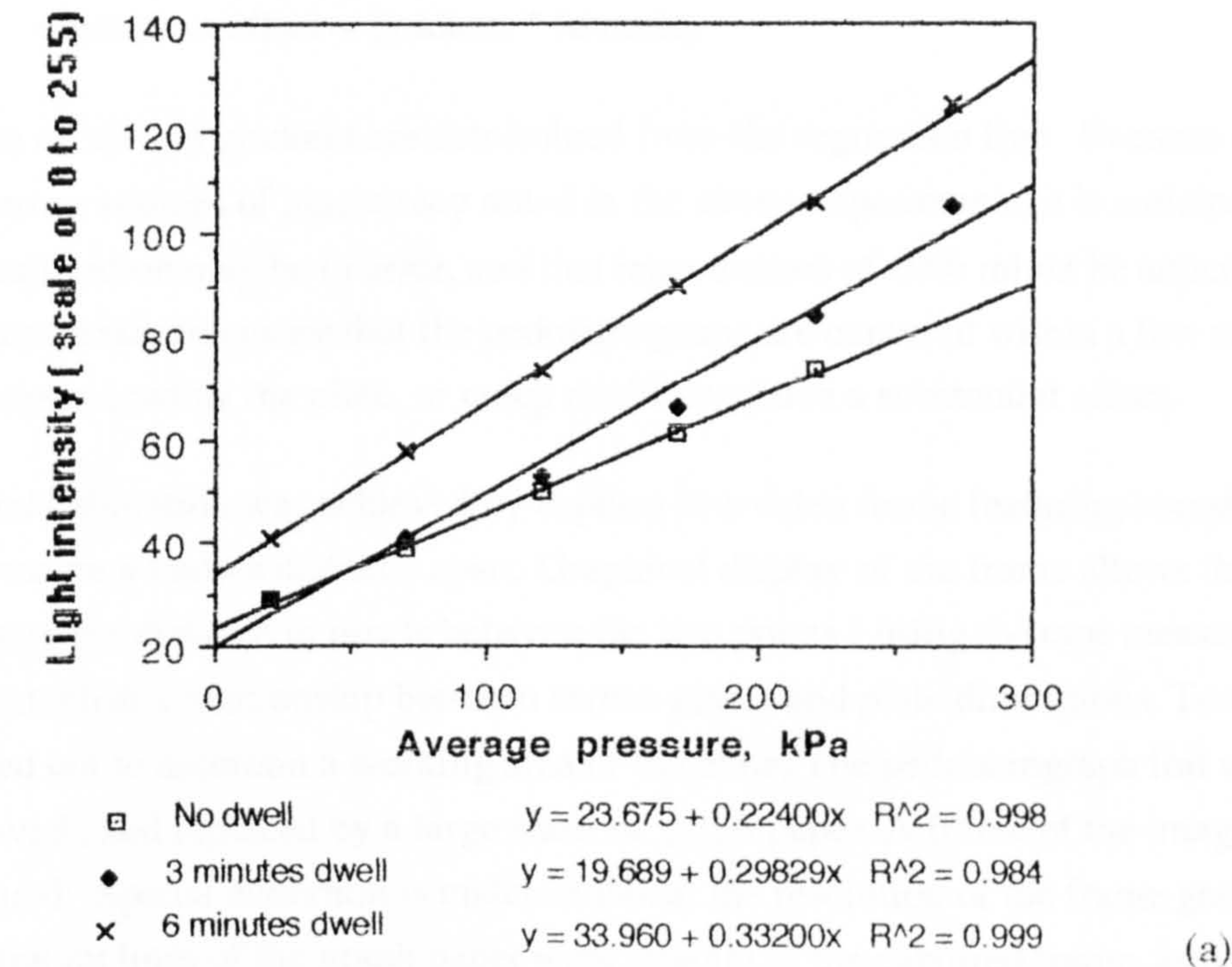


Figure 3.5. (a). Light output vs. applied pressure when the indenter load is applied and held steady for the indicated dwell time, and (b) light output vs time for a fixed applied load equivalent to 220 kPa.

Final calibration:-

Pressure calibration of the transducer was finally carried out by applying increasing dead-weight loading onto a flat-faced indenter with circular cross-section of 100 mm². The calibration curve was derived as in figure 3.4. The computer programme accepts a straight line calibration of the form -

$$\text{pressure} = \text{offset} + \text{gradient} * \text{intensity}$$

where offset and gradient are determined from the regression line. Because of the numerous sources of inaccuracy noted in the above experiments, it is anticipated that this calibration may be in error, and that inaccuracies of 10% might be anticipated. It is also necessary to ensure that the pedobarograms are captured within a few seconds of the person loading the plate, or creep could introduce a substantial effect.

Spatial calibration was achieved by capture of a video frame featuring two sharp points of pressure a known distance apart. Graphical display of the frame allows the user to measure the distance in pixels between the two points (using the tape measure facility) and establish a relationship between screen pixels and plate dimensions. Tests were carried out to ascertain a working area of the plate. The pedobarograph foil was removed , and replaced by a large sheet of graph paper. A frame of the image was captured. Spatial distortion is undetectable at the resolution of the frame grabber ie. the straight lines of the graph paper were straight in the captured frame, as determined by tracking their x,y pixel locations..

Subjects

Patients with a clinical diagnosis of diabetic foot neuropathy and a history of plantar callus were selected from those regularly attending the Diabetic Foot Clinic at King's College Hospital for chiropody. These recordings were made as part of a trial of the effects of debridement of callus described later in this chapter; the records were made as the patient attended for routine chiropodial treatment, and those used in this analysis were taken before callus debridement. Some patients had previously experienced plantar ulceration which was now healed.

Each patient was asked to stand at ease without hosiery onto the pedobaroscope. As soon as the patient was settled and within 20 seconds, a single frame of the video image was captured. The patient's weight was noted, and this was checked against the figure obtained by integration of the pressure under the entire area of the pedobarogram. According to the magnitude of errors anticipated from calibration, an agreement within approximately 10% was expected and checked.

Results

In some, but by no means all, of the patients surveyed very sharp peaks of pressure were observed under the plantar aspects of the metatarsal heads. An example of such a patient is shown in figure 3.6, where the profiles are displayed both under the first metatarsal head (MTH) on the right foot (circle profiles) and across the lateral heads of the left foot (tape profile).

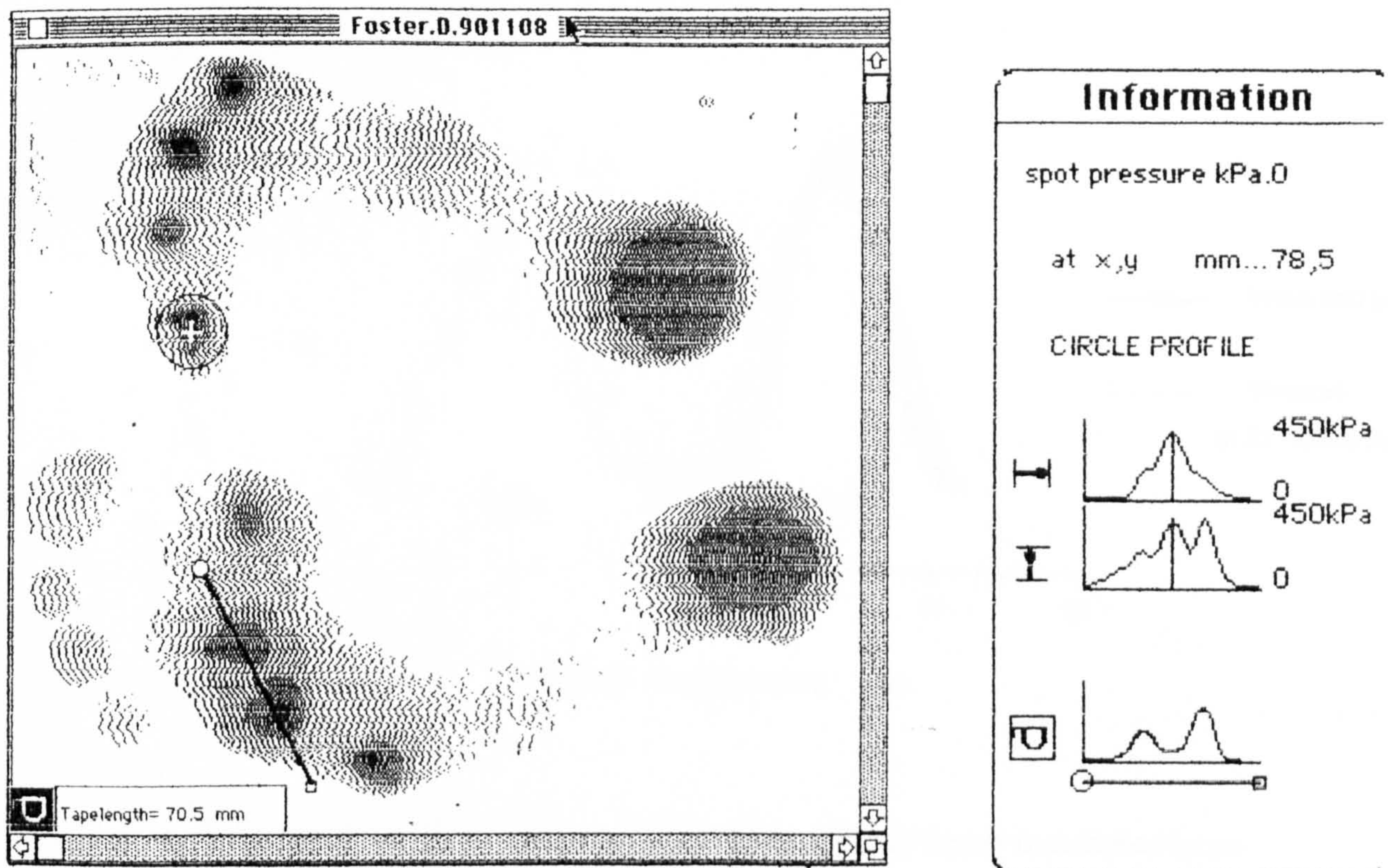


Figure 3.6.A diabetic patient with high peaks of pressure (file FD901108)

The pressure profile under the 3rd and 4th MTHs is plotted out in figure 3.7. An offset sinusoidal wave is superimposed for comparison. The frequency of this fundamental waveform is set by the spacing of the metatarsal heads. For this particular patient the sinusoidal form matches the profile fairly well, although the peaks of the profile are sharper than the fundamental sinusoid. Many profiles were found to be more 'craggy' as for this patient under the right 1st MTH, figure 3.6. Often patients showed only isolated peaks under one or two individual heads.

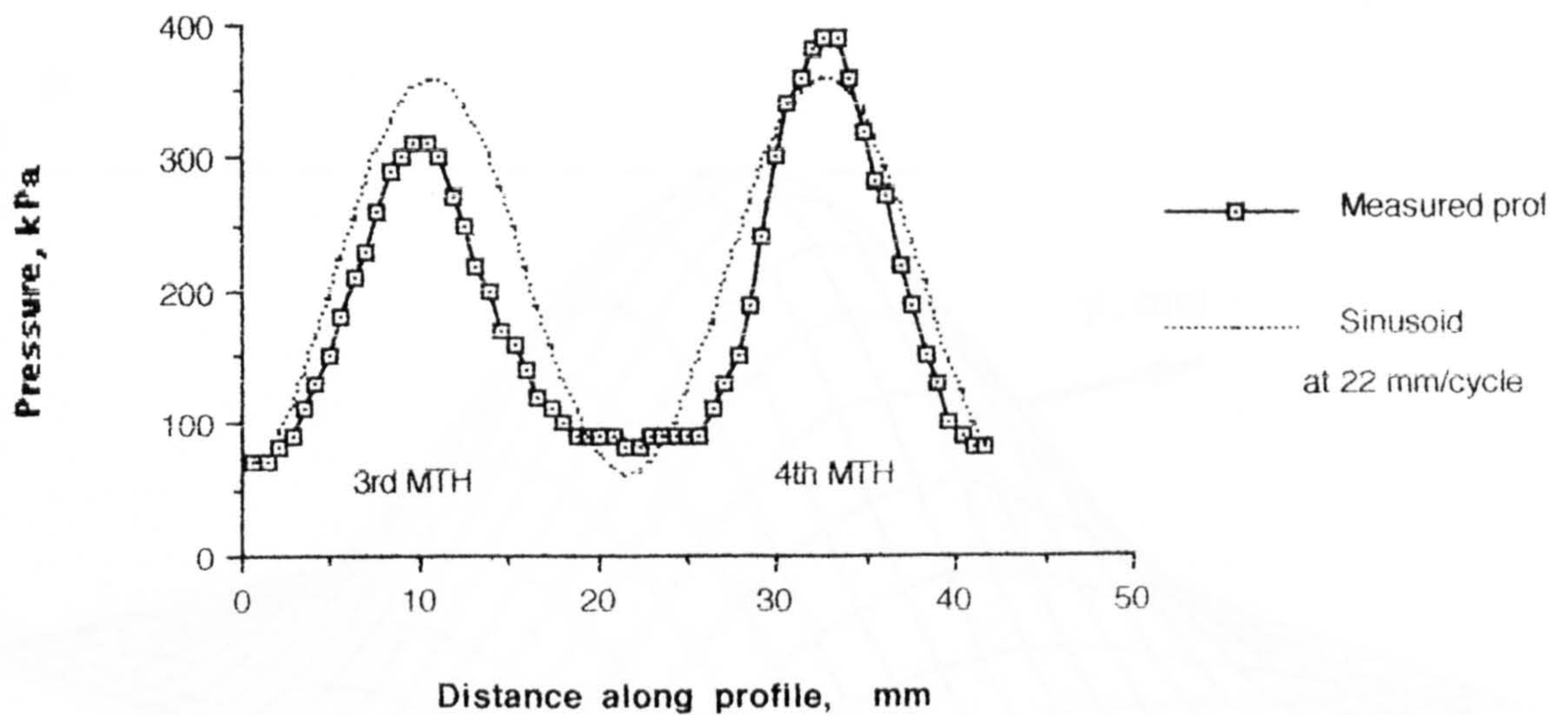


Figure 3.7. The profile under the third and fourth metatarsal heads is matched by an offset sinusoidal form.(file FD901108)

Analysis

The mathematical form of the fundamental frequency can be used to estimate the probable errors introduced by different spatial resolutions of pressure transducers in the following analysis.

Assume that the pressure profile is symmetric in all directions and has the fundamental shape given in figure 3.8 . This can be expressed as

$$p = 0.5 \left(1 + \sin \left(\frac{2\pi}{20} x - \frac{\pi}{2} \right) \right) \cdot 0.5 \left(1 + \sin \left(\frac{2\pi}{20} y - \frac{\pi}{2} \right) \right)$$

eqn 3.1

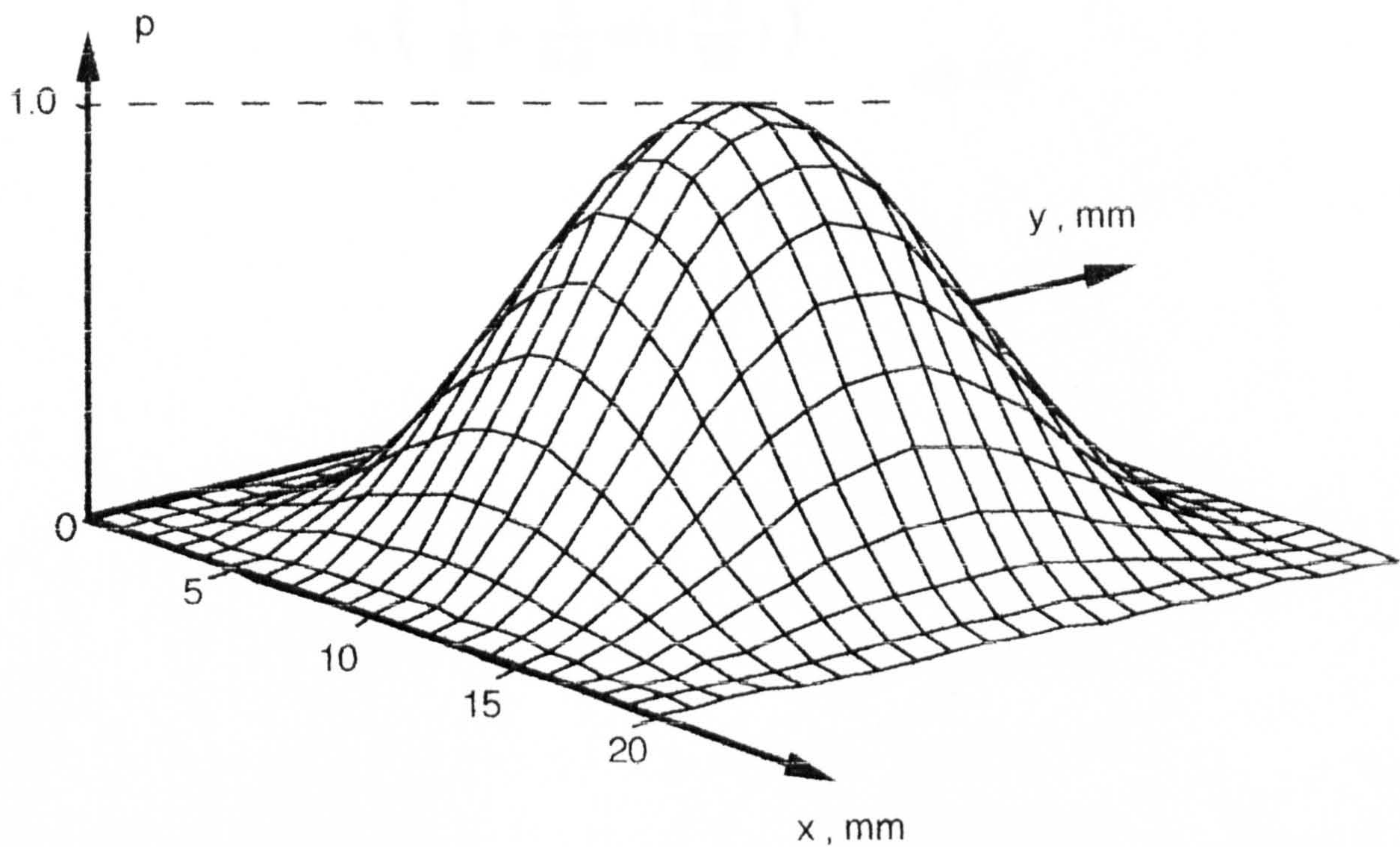


Figure 3.8 3-D representation of a sinusoidal form peak of eqn 3.1.

Assume that the transducer is a square of dimensions $2a \times 2a$. The pressure averaged under a square area centred on the peak of figure 3.8 is given by

$$\begin{aligned}
 \text{average pressure} &= \frac{1}{4a^2} \int_{10-a}^{10+a} \int_{10-a}^{10+a} p \, dx \, dy. \\
 &= \frac{1}{4a^2} \left(x + \frac{20}{2\pi} \cos\left(\frac{2\pi}{20}x - \frac{\pi}{2}\right) \right) \bigg|_{10-a}^{10+a} \left(y + \frac{20}{2\pi} \cos\left(\frac{2\pi}{20}y - \frac{\pi}{2}\right) \right) \bigg|_{10-a}^{10+a} \\
 &= \left(\frac{1}{2} + \frac{5}{\pi a} \sin\left(\frac{\pi a}{10}\right) \right)^2
 \end{aligned}$$

eqn 3.2

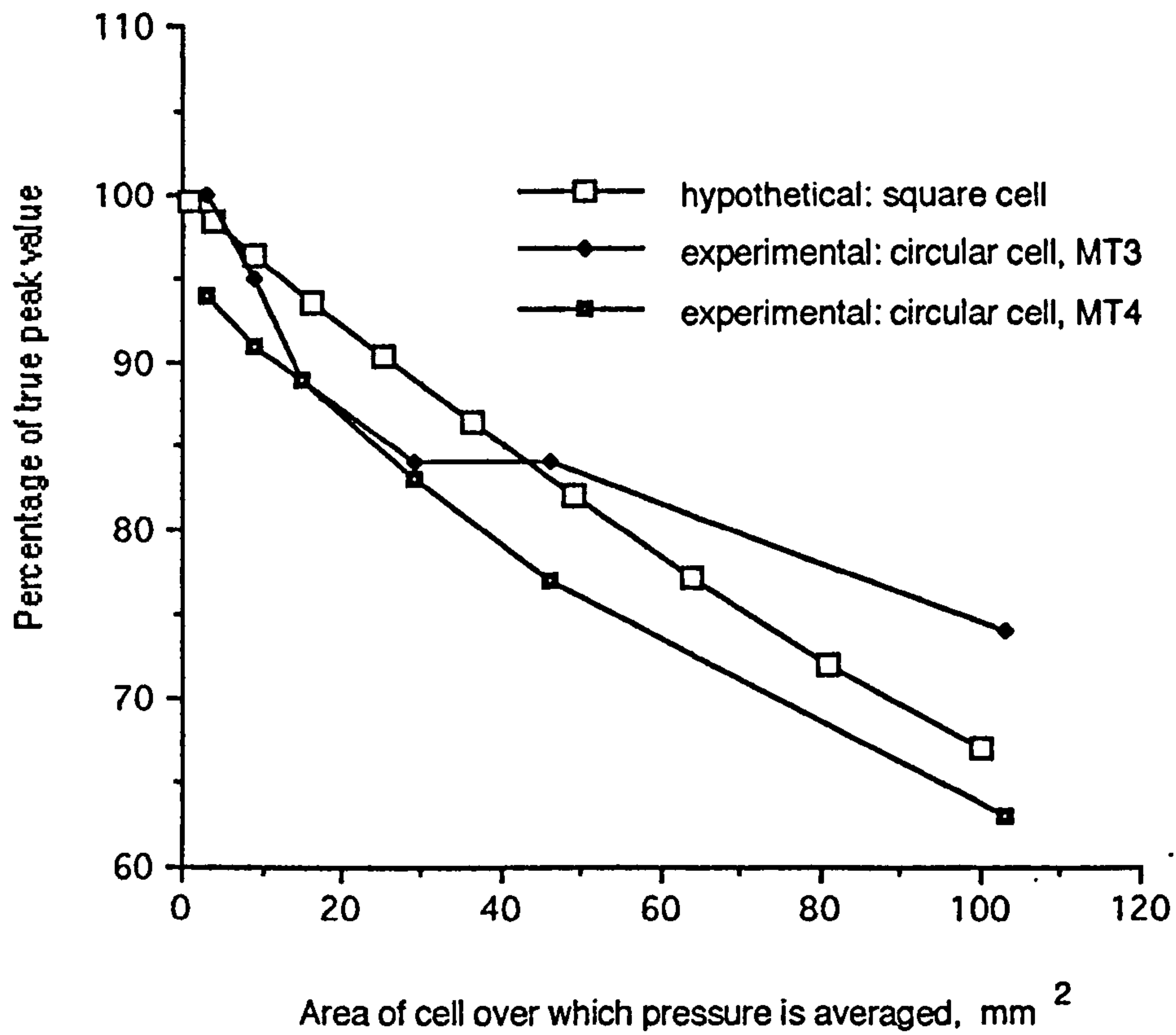


Figure 3.8 b. Comparison of % of true peak pressure readings: for a square transducer under a hypothetical peak, and for circular transducers under experimental peaks under the third (MT3) and fourth (MT4) metatarsal heads: ref. Tables 3.2 & 3.3.

The average pressures which would be recorded from a unit peak by square transducer of various cell dimensions are tabulated below, Table 3.2.

Cell width (2a) mm	Cell area mm ²	Average Pressure on Cell % of true peak
2	4	98.4
5	25	90.3
10	100	67.0
20	400	25.0

Table 3.2. Dimensions of a hypothetical square pressure transducer, and the average pressure on the cell as a percentage of the peak (assuming the cell is located centrally under the profile of figure 3.11.)

For comparison, the pressures under the 3rd and 4th left metatarsal heads expressed as a percentage of the peak are shown in Table 3.3 for the example subject; these figures are derived by use of the circular arena facility in the interactive analysis programme to average the pressure over different nominal areas. Comparing these experimental values with the theoretical predictions above shows a good degree of agreement, Fig 3-8b

Circle area mm ²	Av. Pressure MT3 % of peak	Av. Pressure MT4 % of peak
3	100	94
9	95	91
15	89	89
29	89	83
46	84	77
103	74	63

Table 3.3. The average pressure determined from the pedobarogram (file DF901108).

Discussion

In order to assess the spatial resolution requirements for pressure measurement it is necessary to use a device which itself has high resolution. The pedobarograph is such a device, but suffers from problems of lack of repeatability and difficulty in calibration. It is noted that the pedobarograph can introduce errors at around the 10% level due to factors of creep, hysteresis and uneven response across its transduction surface. These device-specific problems are inherent in the method of optical transduction, and continue to limit the absolute accuracy of this type of device. However, such high spatial resolution cannot be obtained at present from other systems.

For the work described above, considerable care has been taken to ensure that the calibration problems are understood and taken into account. A graphical inspection programme written specifically for this work has facilitated the calibration procedures. Using this programme it is possible to inspect the pressure maps visually, using profiles along graphically-selected lines. These profiles are used as a basis for determining the spatial resolution needed for their accurate representation. Pressure profiles from under the metatarsal heads of diabetic patients have been measured. Often sharp peaks of pressure were observed under discrete metatarsal heads, which agrees with the observations of other workers in this area (Boulton et al 1983).

Inspection of an example profile showed that the waveform approximates to a sinusoidal form , although higher frequency components were apparent both in basically sharper peaks and in raggedness associated with ridges of callus. The fundamental spatial frequency of pressure peaks is dictated by the spacing of the metatarsal heads. Typically spacing might be up to 20 mm for an adult foot. For a smooth profile, it is usual in practice to sample at a frequency of at least ten times greater than the fundamental. The ball-park figure for spatial sampling frequency indicated by this approach would dictate a minimum of around 1 sample every 1-2 mm for an accurate representation. The spatial sampling frequency of the pedobarograph, set by the pixel dimension in the captured video image, is approximately 2 samples per millimetre. The pedobarograph is thus adequate to represent this fundamental frequency.

The effect of low sampling frequencies is demonstrated by the analysis of the relationship between the percentage of peak pressure recorded by various widths of transducer cell under a hypothetical sinusoidal profile matched to an example patient record. It is apparent that use of a cell much greater than 2 mm across begins to introduce noticeable errors between the measured and true peak pressure, given that

these measurement systems are as yet rarely better than 5% accuracy. Larger cells would result in, for example, an underestimation by 10% with a 5 mm x 5 mm cell, and 33% with a 10 mm x 10 mm cell. With a load cell width of 20 mm, the peak pressure is very seriously underestimated by 75% .

The spatial resolution of the pedobarograph commends its use where characteristics of pressure profiles are under investigation and localised peaks of pressure might be expected. This is particularly likely to occur in some cases of diabetic neuropathy and also other conditions such as arthritis. In these cases the fatty pad which usually distributes the load under the metatarsal heads may be either reduced or displaced anteriorly. The bony prominences of the heads acting through skin without the benefit of cushioning leads to the observed sharp peaks. Callus formation can likewise result in ridges of pressure. Studies of the development of such conditions and the significance of the magnitude of the resultant peaks of pressure to causation of skin lesions would require this high sampling frequency for accurate quantification.

3.3 DETERMINATION OF THRESHOLD EFFECTS

Introduction

Many of the devices which measure plantar pressure have a considerable threshold in registration of low pressure. This is either due to a physical limitation in sensing the pressure, or to a threshold which is introduced to remove the effects of noise around zero pressure readings. The Tekscan system used in Case Study II described below for example, is based on force sensitive resistor technology and has a threshold of between 20 kPa and 30 kPa (this has been reduced somewhat in a later modification). It is noted that this is in fact about the average pressure under the foot standing on a flat surface. The pedobarograph used in our experiments has background noise of the order of ± 5 kPa used as described above, necessitating a threshold cut-off of this order.

Threshold is not an important factor if a device is used only to study the magnitudes of high pressure. However this effect can become significant when the device is used to study the area of contact of the foot with the floor. The area of contact is often of interest in insert design since the stated aim of some orthoses is to increase the area of support - thereby supposedly reducing the pressures for the same load. Other measures derived from the area, such as the total load derived from integration of pressure and area, are likewise susceptible to threshold effects.

The pedobarograph can be used to study threshold effects since it provides a continuous signal from the dark background (representing zero pressure) through to lighter areas (representing pressure). The device does however suffer from a degree of noise on the light signal which must be taken into account.

Method

The records of three patients with diabetic neuropathy were used for analysis. Patient S1 is overweight with generally high pressure under both feet and some discrete peaks of up to 330 kPa under the metatarsal heads and the toes of one foot. Patient S2 shows no particularly high pressure areas, and tends to stand with the weight on the heels. Patient S3 exhibits a fairly abnormal pattern, with considerable loading in the midfoot, and very high pressure under the first metatarsal head on the left foot (480 kPa) and toes.

A pedobarogram was analysed for each subject to determine the apparent area and integrated load at simulated threshold levels. Firstly, the intensity of the background was checked using the spot intensity function. This was found to lie, as expected, at a mean value ± 1 light unit, with occasional values of ± 2 especially at the edges of the plate and no values outside this range. The pressure calibration threshold was set to the mean value + 1. The 'Load Statistics' option was then invoked from the 'Function' menu. This performs an integration over the area of the pedobarogram to yield (i) the total area above the threshold value, and (ii) by summation of the product of each pixel area and its pressure level, the total load on the pedobarograph. It is possible to apply an arbitrary cut-off value in the Load Statistics option: this does not affect the pressure calibration, but pixels at a light intensity below the threshold plus cut-off value are not included in the integration. A series of load statistics were derived for increasing values of cut-off from 1 to 10 light units.

Results

The results are graphically presented in figures 3.9 and 3.10. With regards to the area plot, it must first be noted that the apparent area at zero cut-off is probably a result of noise on the pedobarogram, which causes a small percentage of the background pixels to register as positive pressure. The difference of almost 50% of the area with a cut-off of 2 light units shows that the pedobarograph must be used very carefully for area calculations.

However, above a cut-off of 2 light units the continuing downward trend of the curve can be ascribed solely to the exclusion of genuine areas of the footprint. The fall off is of the order of 5-9 cm² per light unit, or 40 - 70 cm² for a threshold of 20 kPa. Noting that the average support area for a normal female may be approximately 200 cm², then this clearly represents a very large potential error of 20-35%.

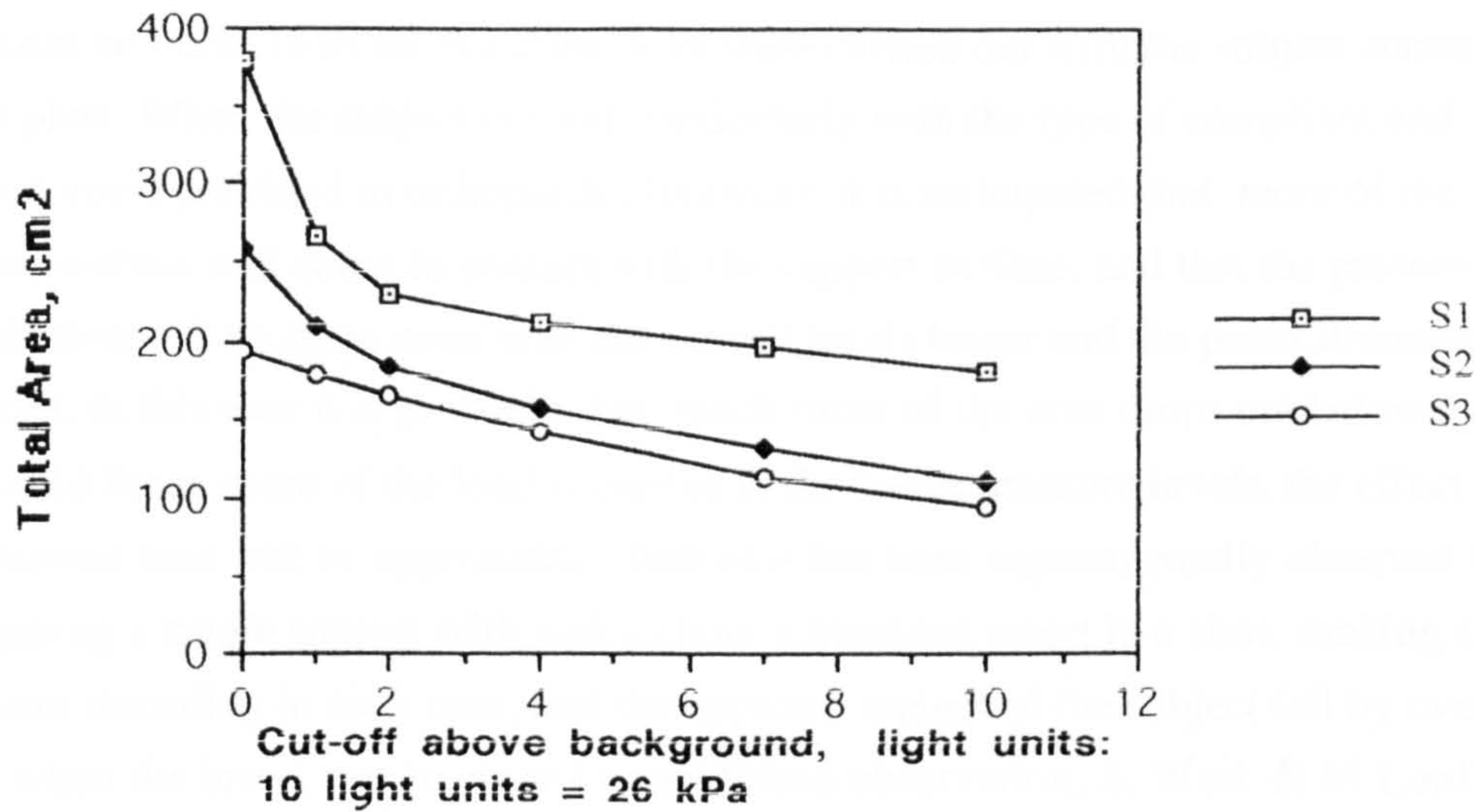


Figure 3.9 Area derived by integration from a pedobarogram using a cut-off value to simulate threshold effects: patients S1, S2 and S3.

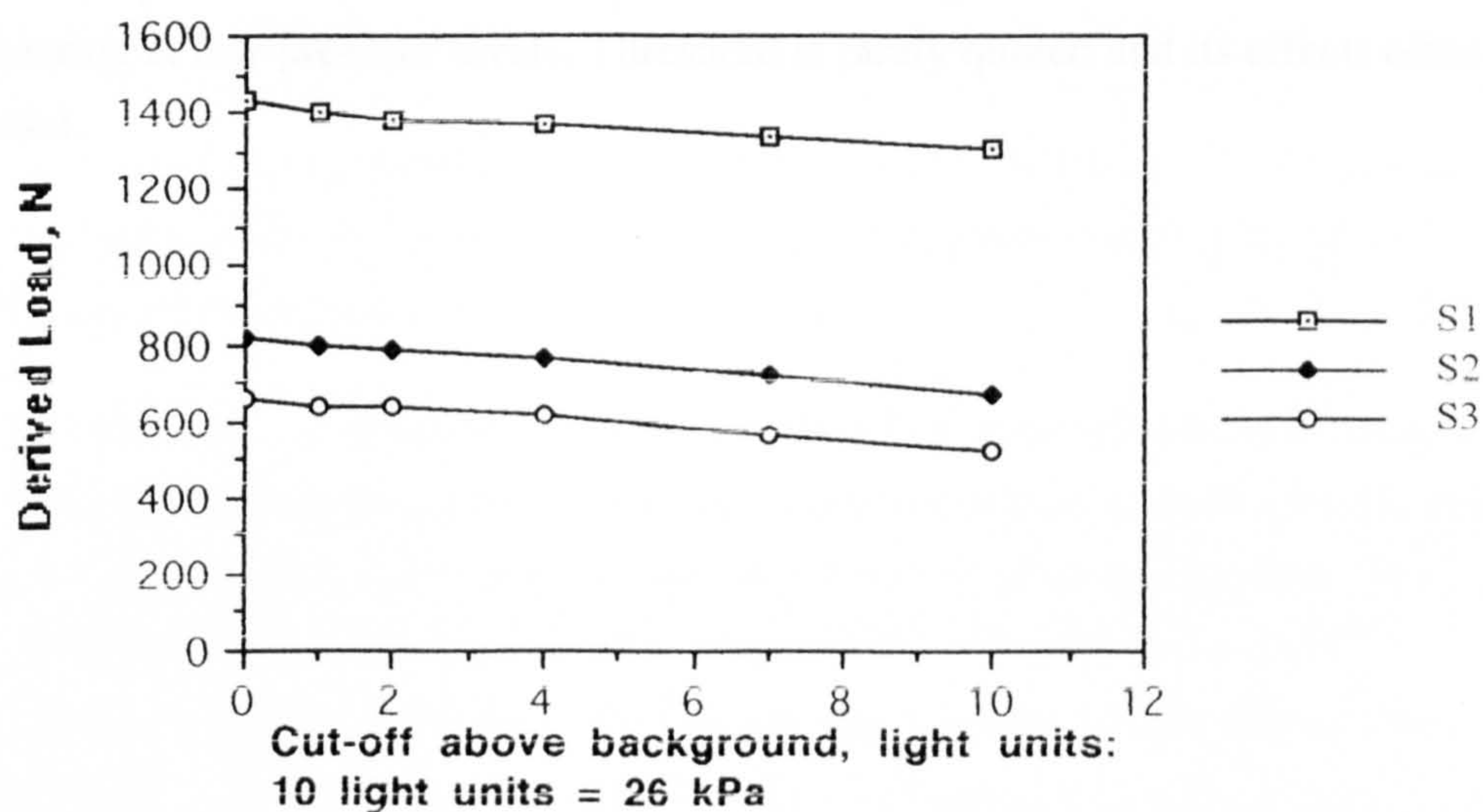


Figure 3.10. Load derived by integration from a pedobarogram using a cut-off value to simulate threshold effects: patients S1, S2 and S3.

The load plots are less sensitive to threshold, showing a decline in derived load with simulated threshold of approximately 80 N for 20 kPa, which now represents only 10% of an 80 kg person. This is because the loading is mainly concentrated in areas of higher pressure. Nevertheless the effect is also not inconsiderable.

Discussion

It should be borne in mind that these tests were carried out with the subject standing on a flat plate. When the subject is shod, particularly with the type of compliant and shaped insert provided in orthopaedic footwear, it is anticipated that more of the plantar surface will come in contact with the support surface, and that the pressure distribution will be more even with the overall levels lower and the peaks dramatically reduced. In this case it is probable that much more of the area drops out below the threshold. Since more of the load is carried at the lower pressure levels, the effect on the derived load will be appreciable. Indeed it has been experimentally observed by comparing a single subject with and without a moulded insert in a shoe, making a Tekscan recording in each case, that the apparent weight of the subject fell by over 25% when the insert was in place (unpublished observation, S. West & M Lord) but reliably increased again when the insert was removed .

It is concluded that the threshold of measuring devices must be taken into account when deriving areas of contact or weight by integration of pressure measurements. Threshold of the order of 20 kPa are not uncommon in measuring devices, and these may give errors of the order of 20% (area) and 10% (weight) with barefoot standing: with in-shoe pressure measurements the effects are magnified because of the increased load-bearing at low pressure levels. Threshold is rarely quoted and its effects often neglected.

3.4 CASE STUDIES

I High Pressure and Presence of Callus under the Diabetic Neuropathic Foot.

A preliminary study was conducted in collaboration with the staff of the Diabetic Foot Centre at King's College Hospital into the correlation of high pressure and the presence of callus. The study was designed to evaluate whether debridement of callus (surgical removal) would cause a reduction in peak plantar pressures under the standing foot. This information could be of clinical significance in proving the need for regular debridement of such callus to prevent or discourage the formation of plantar ulceration.

A pilot patient was studied in detail (this patient was used as the basis of the pressure profile measures in the previous section, figure 3.6). The patient is an active 49 year old insulin-dependent male diabetic with a long history of neuropathic foot complications, excision of the 2nd ray and loss of fatty pad under the metatarsal heads. He has previously had plantar ulceration under the right PMP1 and PMP4, but has none at present.. He now remains free of ulceration by attending for routine debridement of excessive callous every few weeks..

The plantar pressure distribution under the standing feet was collected immediately before and after routine debridement. On each occasion that the patient attended clinic, the patient stood barefoot on a pedobarograph before and after debridement. The before and after images were inspected for comparison. Overall, the weight distribution was slightly different in the two images, with the weight shifted more forward on the right foot. This should be taken into account in comparison of peak pressures under the callosities, which may vary from one record to another due to stance alteration.

An analysis was derived which compares both the absolute value of the peak pressure under a given metatarsal head, and the ratio of the peak pressure to the average pressure in the region of the head.

The PBG analysis programme was used to inspect the local spot pressure and also to display the average pressure under a circular arena. By dragging the arena under each

callosity in turn, and scaling the size to cover the general area of the relevant metatarsal head as shown in figure 3.11, a figure for the average pressure in the PMP region was determined. This average pressure is an indication of the total load transmitted through the metatarsal head. The peak pressure for each area was also noted.

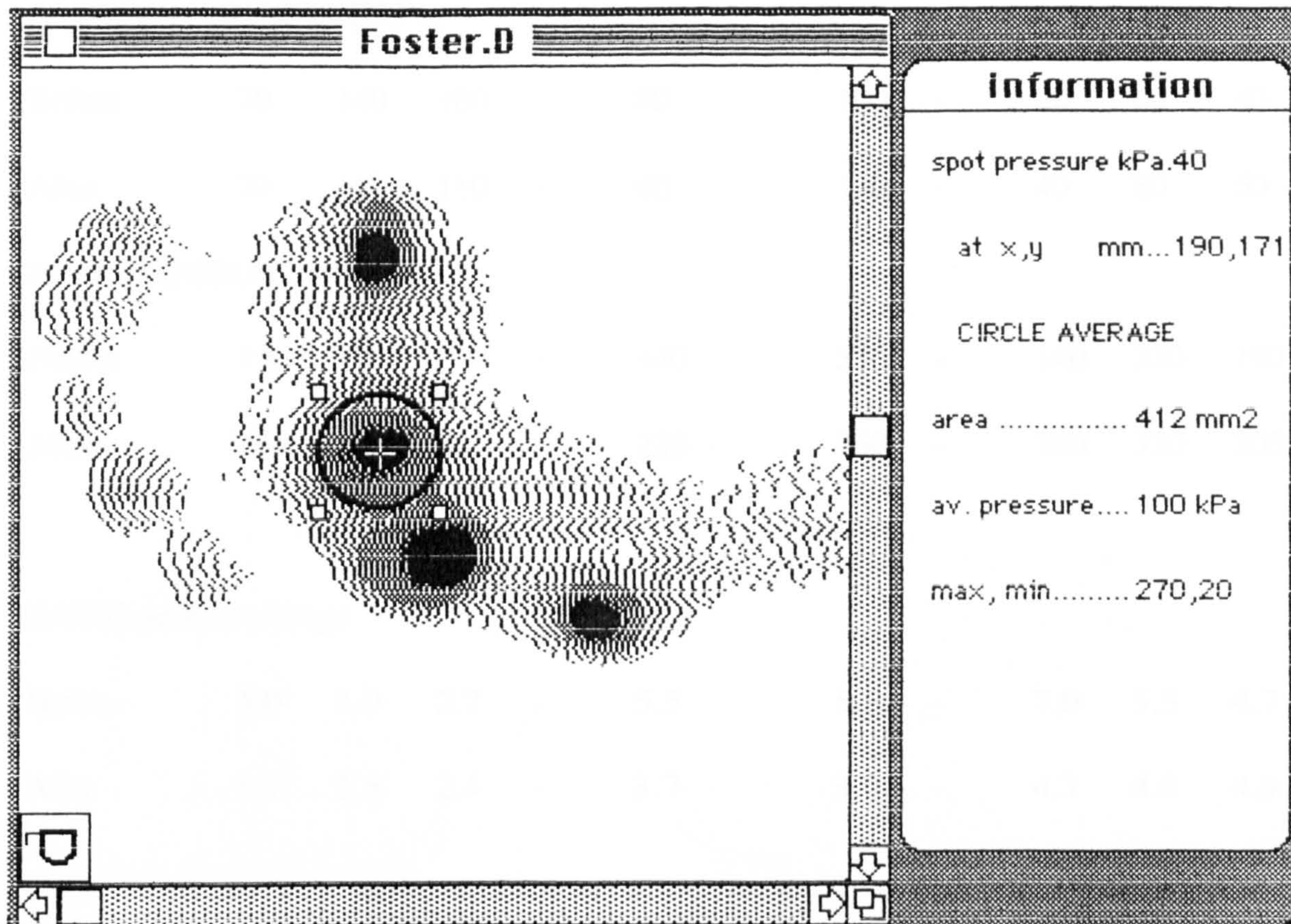


Figure 3.11. Example of determination of average and peak pressure.(file fd: disc 5)

Table 3.4 compares the values before and after debridement. Under four of the callosities (left PMP 1,4,5 and right PMP 1) there is a dramatic reduction of peak pressure by between 25% to 50% while the average pressure in the region remains fairly constant. On the remaining area of right foot forefoot, the general pressure levels are higher due to a different stance, and this is reflected in higher average pressures; however the peak pressures are either fairly constant or reduced. The pressure profile across PMP1 are compared in figure 3.12, and show how the peaks have been flattened.

LEFT FOOT						RIGHT FOOT				
MTH	5	4	3	2	1	1	2	3	4	5
AVERAGE PRESSURE kPa										
Before	70	140	100	-	80	100	-	20	60	40
After	70	110	110	-	60	120	-	40	80	50
PEAK PRESSURE kPa										
Before	350	420	270	-	440	550	-	140	330	190
After	260	280	260	-	220	360	-	190	320	200
RATIO peak to average										
Before	5.0	3.0	2.7	-	5.5	5.5	-	7.0	5.5	4.7
After	3.7	2.5	2.4	-	3.7	3.0	-	4.7	4.0	4.0

Table 3.4 Comparison of plantar pressures under the five metatarsal phalangeal joints before and after debridement. Average pressures were taken over a 412 mm² circular area.

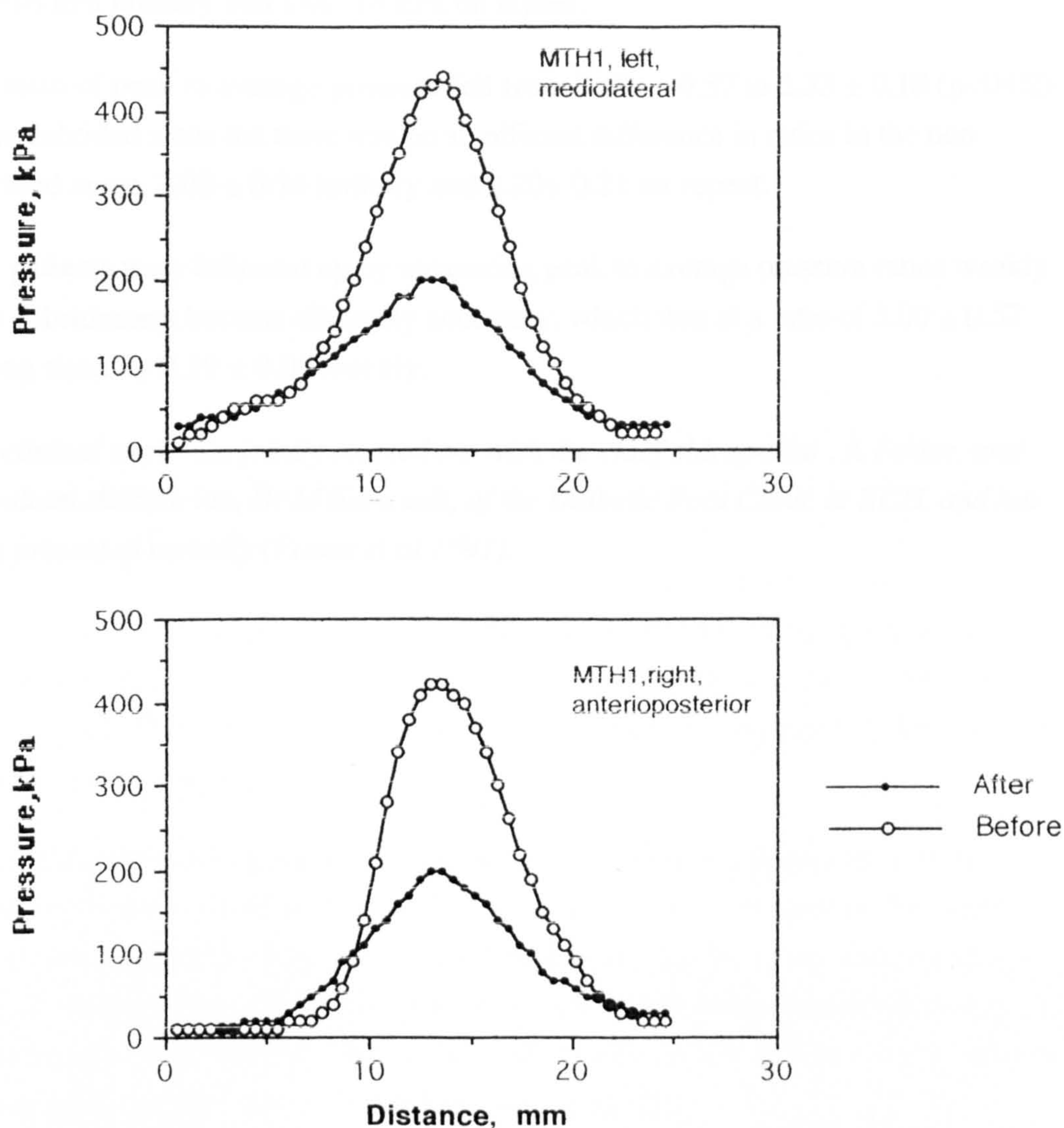


Figure 3.12. Comparison of the pressure profile under the first metatarsal head before and after debridement of callus.

These results indicate that debridement has appreciably reduced the peak pressures under callosities, although the total load borne under each metatarsal head remains constant.

A pilot study of ten patients was then carried out following the same protocol. The patients, mean age 52.8 years (38-75 years), with a history of neuropathic ulceration were assessed before and after routine debridement of callus. The regions which were debrided were noted at the time.

Peak pressure fell from 396 ± 61 kPa (mean \pm standard deviation) to 243 ± 33 kPa, $p < 0.01$ under the metatarsal heads that needed debridement. In contrast, peak pressure

under the metatarsal heads that did not need debridement was unchanged at 185 ± 16 kPa initially and 184 ± 18 kPa on repeat.

The ratio of peak to average pressure fell from 3.59 ± 0.57 to 2.33 ± 0.18 ($p < 0.02$) in the debrided areas but there was no significant difference in ratios in the non-debrided areas, 2.09 ± 0.14 initially and 2.20 ± 0.21 on repeat.

Five patients were followed up by measuring peak to average pressure ratios weekly until debridement became clinically necessary, which was at a ratio of 3.00 ± 0.57 having risen by 0.19 ± 0.09 weekly.

The clinical work was jointly carried out with the chief chiropodist, A Foster, and consultant diabetician, Dr M Edmonds, of the Diabetic Foot Clinic at KCH, and has been presented verbally (Foster et al 1991).

II.Determination of Location of High Pressure in the Metatarsal Region for Purpose of Insert Design.

Palpation of the metatarsal heads (examination by touch of structures under the skin) is often used to obtain bony landmarks for purpose of location. With the foot in a neutral position, the sole of the foot is marked with a felt pen under each palpated head, and the marks are transferred onto a card insole within the shoe during walking. The card insole is then used as a template, for example as a guide for the positioning of metatarsal domes. These are frequently used to relieve excess pressure under the metatarsal heads. The dome may be part of the shaping of a moulded insert, or it may be a separate commercially-available item which is attached over a flat insert, just posterior to the line of the metatarsal heads. It is thought that the dome is effective because the load is transferred back onto the shaft of the metatarsal, and also because the cramped shafts are separated mediolaterally by the establishment of a transverse arch. For effective action then, the positioning of such shaping needs to be done with reference to the anatomy of an individual foot.

The method of palpation has shortcomings. Firstly, there is a degree of observer variability in the position marked on the skin. Preliminary tests however indicated that the positions marked by three experienced clinicians when using the same technique were all within 5 mm. More serious is the suspicion that the motion of the skin relative to the bony structures during gait leads to a considerable discrepancy between the real and presumed positions of the metatarsal heads.

The exact positioning of the shaping features of the inlays with respect to the marks is a matter of subjective judgement at present. It is suspected that this is in part due to the unreliability of the reference positions obtained by palpation. It must be noted that in continental Europe it is common to use a pressure map instead, for example using a modified Harris and Beath mat where the subject stands onto an inked printing pad. The peaks of pressure are quite reasonably assumed to correspond to the location of the metatarsal heads. For future use in a computer aided design system, a quantifiable standard is required to achieve the best results.

This study is concerned particularly with the accuracy of the method of palpation for location of the metatarsal heads. Specifically the location is to be investigated at the push-off phase of gait when the pressures in the metatarsal region are greatest and the need for pressure relief the most acute. Working on the reasonable assumption that the metatarsal heads overly the areas of peak pressure in this region, the position is

determined from dynamic pressure maps in addition to the standard palpation method . A comparison to the palpated locations is then made.

Method

The F-Scan Gait Analysis System (previously referenced) was used to measure the pressure maps between the foot and shoe insole. This system provides a thin flexible pressure sensing insole for placement between the foot and shoe; 960 load cells on the surface of a standard sized insole are spaced 5 mm apart, Figure 3.13. An insole was trimmed and inserted into the shoe with the handle of the insole inserted into a cuff unit attached above the subject's ankle using velcro straps, Figure 3.14. The cuff unit provides pre-amplification, signal conditioning and A/D conversion as each individual sensing point is polled at 50 Hz. A coaxial cable link interfaces the cuff unit to a PC which stores 4 s of data.

A group of 6 asymptomatic subjects (20-45 years, 3 F) were studied wearing their own flat-heeled shoes, which ranged from lace-ups to slip-ons. The location of the areas of peak direct pressure were found using both the indirect method of palpation and the direct method of F-Scan recording, taking the central steps of three trial walks for each subject.



Figure 3.13 The F-scan insole



Figure 3.14 Insole and cuff on subject

Results and Analysis

Inspection of the pressure records was carefully carried out to determine the location of the peak pressure under each metatarsal head. The F-Scan analysis package allows for the definition and positioning of up to four 'boxes' over an area of interest, where each box is 3 by 3 cells ie. 15 mm square. The average pressure in the boxes can then be plotted vs. time out over the trial walk, figure 3.15. (The plot was generated by outputting the F-scan data from the boxes under the 1st to 4th metatarsal heads into an ASCII file, adding the data for the total resultant vertical force, and plotting the combined data from another graphing package (CricketGraph)).

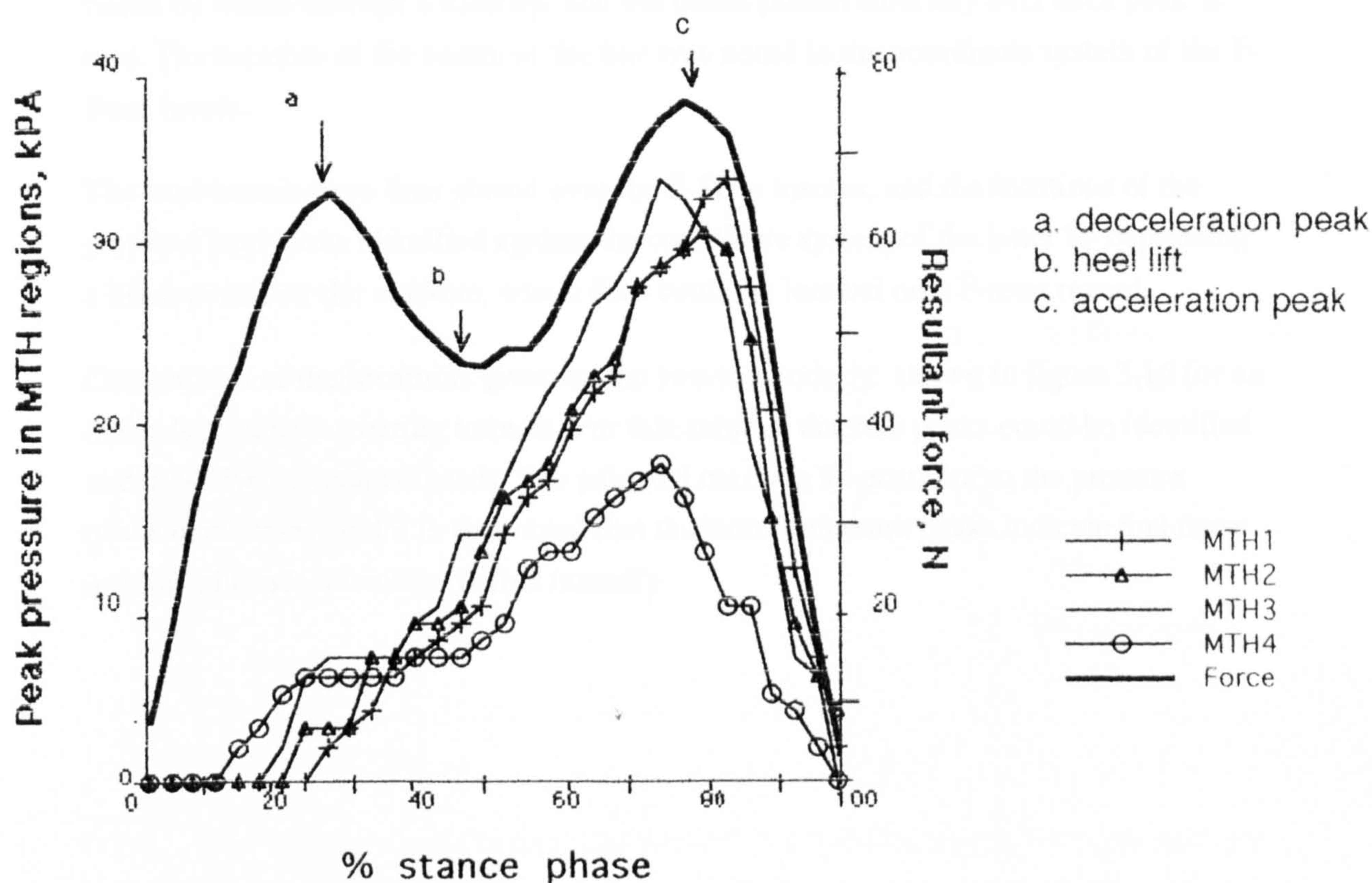


Figure 3.15 Plot of the peak pressures under metatarsal head regions, and the total resultant force under the foot, in a single step. The point of heel lift, b, was determined from the pressure maps when the heel imprint first disappeared.

It was noted that it takes some experience and subjective judgement to identify the pressure peaks of an individual metatarsal head. Usually the pressure peak under first head can be clearly identified, but those under the second and third head often merge:

the region of the fourth head can easily be mistaken for the fifth: and a peak under the fifth head may not be apparent. In order to assist in the identification, timing cues were used. Notably, after heel strike, the fifth and fourth head regions appear before the more medial three heads, and the pressure tends to build up during foot flat phase and reach a plateau around the so-called decelerating peak, 'a'. This is compatible with the heel and midfoot being used as the flat platform during this phase. After heel lift, the pressure increases again in synchrony with that under the medial heads, figure 3.16. It is noted that the pressure peaks in the acceleration phase, 'c', tend to occur in the order 1,2,3 and 4, although they were sometimes so close together in timing that this could not be used as a reliable indicator.

The middle walk was used in each case for analysis. Each record was investigated frame by frame through a footstep, and the boxes placed carefully over each peak in turn. The location of the centre of the box was noted in the coordinate system of the F-Scan insole.

The card inserts were then placed over the F-Scan insoles, and the locations of the palpated landmarks identified against the coordinate system of the latter by depressing a blunt pencil on the markers, which then could be located on a F-scan record..

Comparison of the locations given by the two methods is shown in figure 3.16 for an individual subject wearing trainers. For this subject, discrete peaks could be identified under all five metatarsal heads. The palpated markers lie posterior to the pressure peaks in all cases, and it is also noted that the lateral pressure peaks indicate that these metatarsal heads have also shifted laterally.

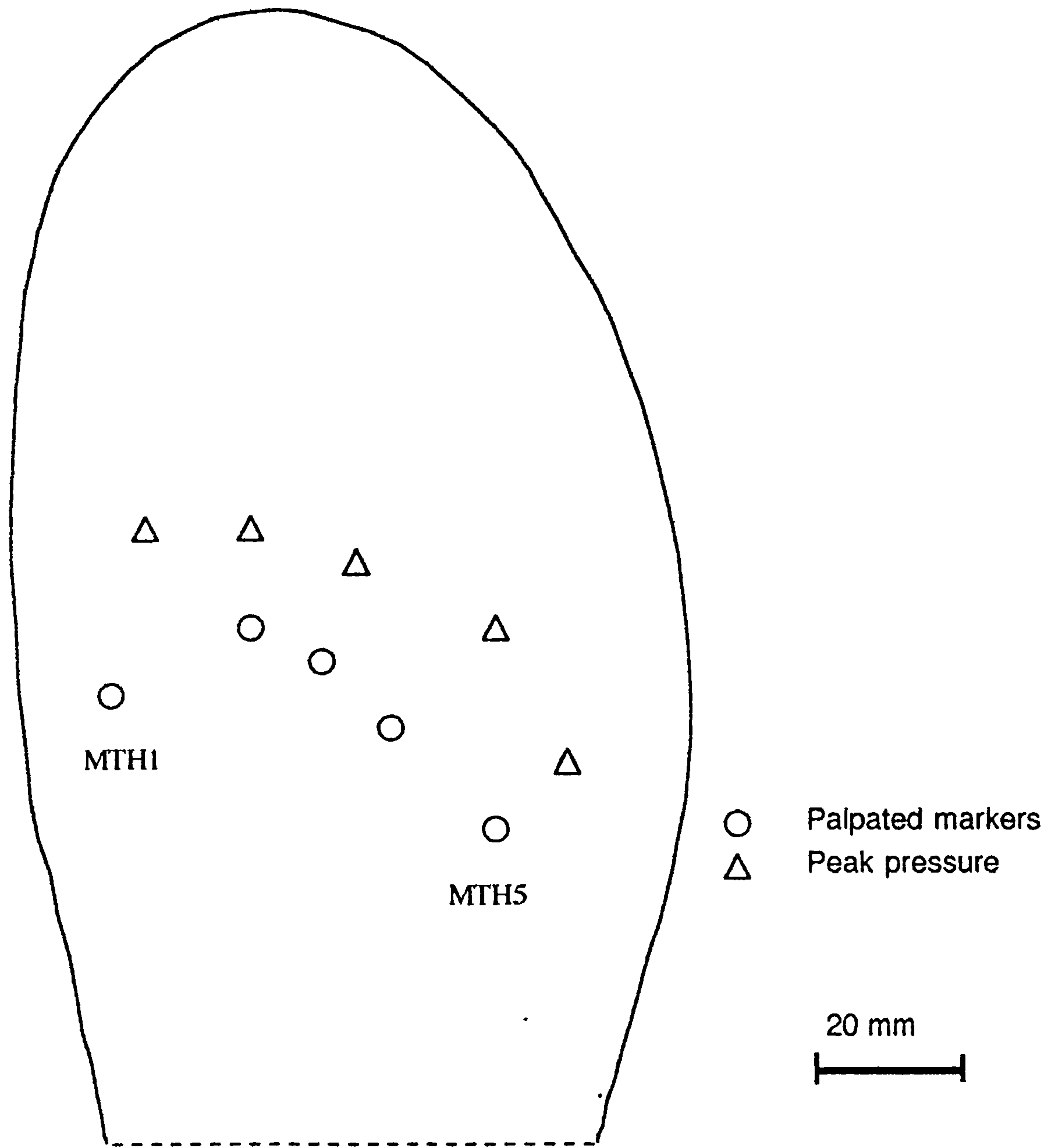


Figure 3.16 Comparison of the palpated markers and the locations of peak pressure for an individual male subject wearing trainers. The outline indicates the shoe insole, the card and the F-scan insole contours.

Subjects	MTH1 AP	MTH1 ML	MTH2 AP	MTH2 ML	MTH3 AP	MTH3 ML	MTH4 AP	MTH4 ML
S1	25	0	15	0	20	- 5	20	-10
S2	20	0	25	0	20	0	15	0
S3	15	0	15	0	20	0	20	0
S4	20	5	30	0	30	0	20	0
S5	25	0	10	0	20	- 5	20	0
S6	25	- 5	15	0	15	- 5	15	-15
Average shift, mm	21.7	0.0	18.3	0.0	20.8	-2.5	18.3	-4.2
St. Dev, mm	4.1	3.2	7.5	0.0	4.9	2.7	2.6	6.6

Table 3.5 The mean shifts of the markers under the 1st to 4th metatarsal heads from the location of peak pressures for six subjects: accuracy ± 5 mm: directions as indicated on figure 3.16.

The shifts for all six subjects have been tabulated in Table 3.5, omitting the fifth head which could not be consistently located in the pressure maps. This demonstrates that the indirect method of palpation substantially mislocated the area of peak pressure by approximately 20 mm in the anteroposterior direction; a mean lateral shift for the 4th head was not significant for this small number of subjects.

Comparison of another group of four normal subjects was made by Lord et al (1992) using the above protocol, as part of preliminary work to decide on a suitable location for discrete shear transducers. The subjects were all of similar footsize (7 1/2 UK) and could comfortably fit the same pair of shoes. The results are shown in figure 3.17 . By using the same shoes, the traces could be overlaid in a meaningful way. The behaviour discussed above is clearly continued with these four subjects, ie, the pressure peaks lie anterior to the palpated location of the metatarsal heads

The sensitivity of load measures to this mismatch was quantified by comparing the pressure under the palpated markers to the maximum for each head. Using the analysis facilities of the F-scan software, the (average) pressure in each 15 mm x 15 mm box, was recorded in both locations, the results are shown in figure 3.18. The peak pressure under the palpated markers was on average only 50% of the true peak recorded for each respective head.

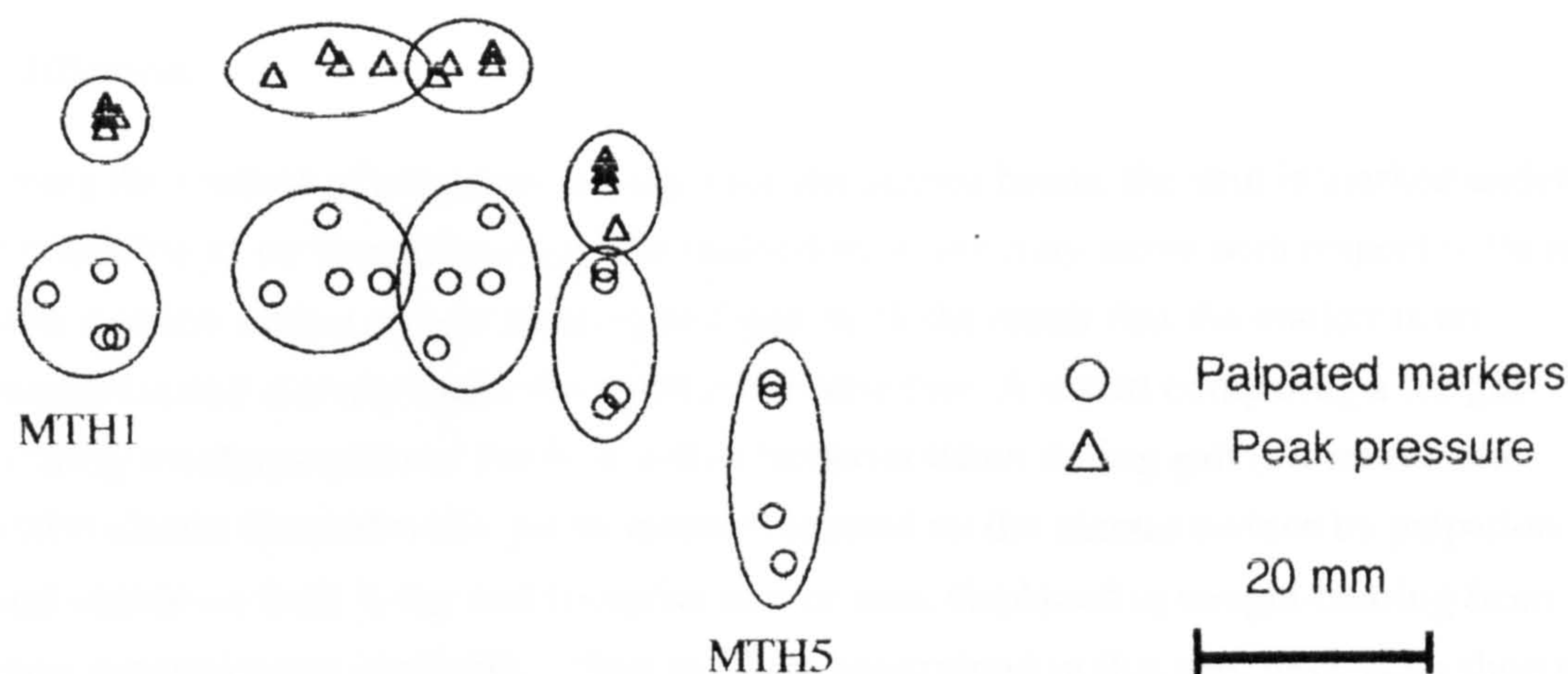


Figure 3.17 A composite of four subjects who all wore the same pair of shoes. The oval outlines are drawn to group together the markers or pressure peaks associated with each head. Where triangular symbols indicating peaks were overlaid (the F-scan locations lie on a fixed grid at 5 mm centres) these have been staggered by 1 mm for clarity. Peaks of pressure were not detected under the fifth head in this group.

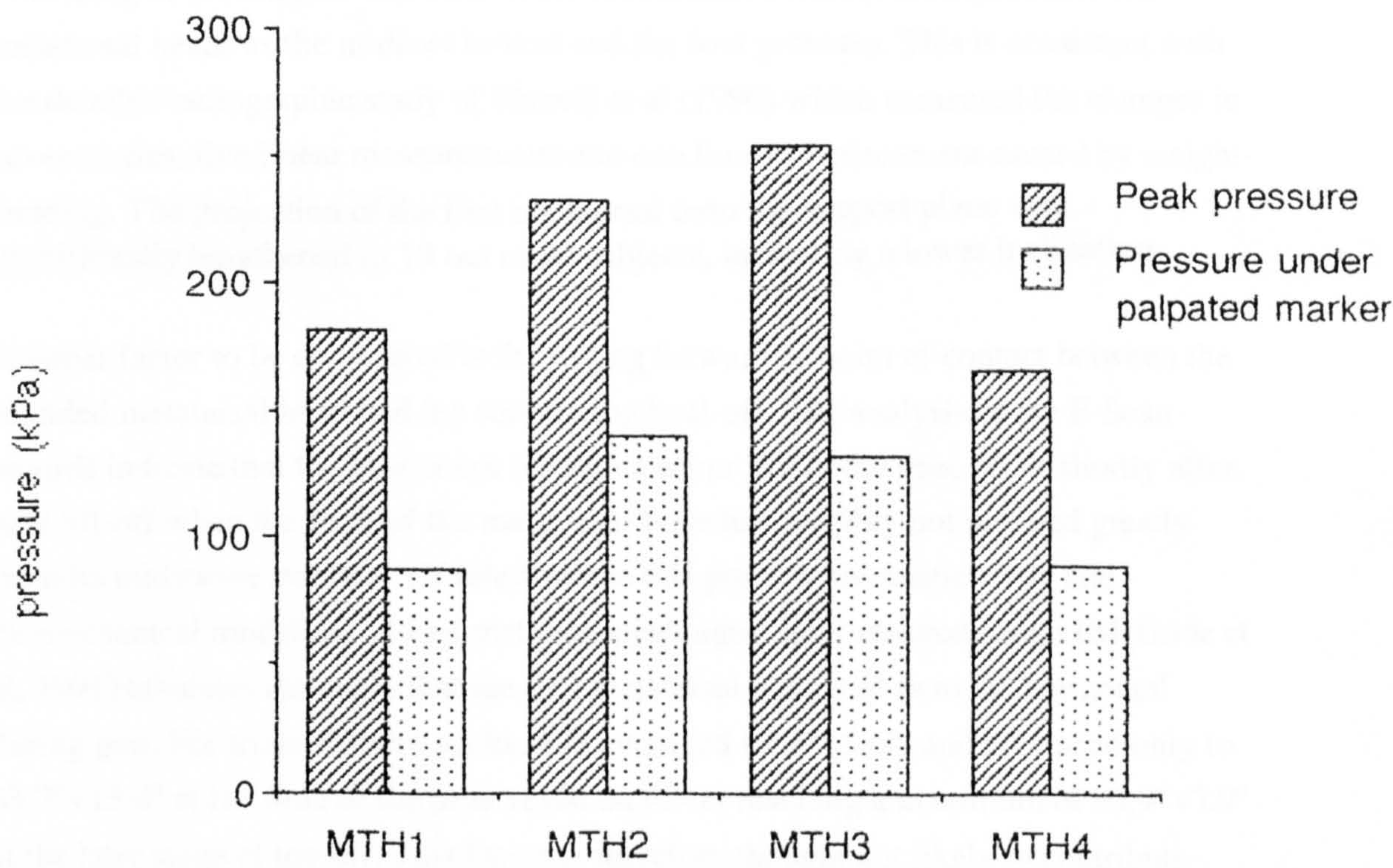


Figure 3.18. Comparison of the mean peak pressure to the pressure under the palpated marker (n=6).

Discussion

Using the method of palpation to locate the metatarsal heads, the skin is marked under a condition of no weight bearing. The skeletal structure may move with respect to these skin markers during weight-bearing and gait, with the result that the marker is no longer located directly under the appropriate structure. A report comparing a weight-bearing roentgenogram of the foot with a footprint taken during gait (Weavers et al, 1989) clearly illustrates this point: markers located on the plantar surface by palpation and visible on both X-ray and footprint can be seen displaced in weight-bearing from their notional bony landmark. Skin markers determined in this way have been shown to be on average in a position which was 20 mm posterior to the true location of the peak, table 3.3. There are several factors which might be considered responsible for this discrepancy.

The landmarks are palpated with the foot non-loadbearing. When the foot is progressively loaded the skin will tend to remain in the position at which it first came in contact with the shoe sole, whereas the underlying bony structure will distort. Flattening of the longitudinal arch of the foot results in an anterior motion of the metatarsal heads as the midfoot lowers and the foot pronates. This is consistent with the detailed radiographic study of Shereff et al (1990) which measured the changes in seven angles, five linear measurements and one linear displacement caused by weight-bearing. The projection of the first metatarsal onto the support plane was significantly lengthened in 19 out of 20 subjects, indicating a lower inclination.

Another factor to be considered is the rolling forward of point of contact between the rounded metatarsal head and the sole during heel-off. The analysis of the F-Scan records indicates that the maximum pressures occur just at the time of, or shortly after, heel lift-off when the shaft of the metatarsal bone has possibly not inclined greatly from its midstance position. Of relevance to this point, a kinematic study and biomechanical modelling of first metatarsophalangeal joint reaction forces (McBride et al, 1991) tabulates the angle that the first metatarsal bone makes to the horizontal during gait. For trials without socks, this averaged $61.3^{\circ} \pm 5.6^{\circ}$, and increased only to $63.7^{\circ} \pm 13.4^{\circ}$ at the time of the peak resultant force, reaching a maximum of $93.9^{\circ} \pm 7.9^{\circ}$ at the later stage of toe-off. This factor is therefore thought not likely to contribute greatly to the shift in peak pressures.

Finally, shearing forces may cause a relative motion between the skin and bony structures (considered in more detail below). In barefoot gait, the acceleration force which occurs at push-off and can be recorded for example on a Kistler force plate must result in shearing at the plantar surface of the foot. At the time of push-off the

resultant shear force over the forefoot and toes is in the forward direction on the foot, which would cause the metatarsals to move posteriorly relative to the plantar surface and would tend to give a posterior shift to the pressure peaks. This is the opposite to the observed result. It must be noted that in shod gait, the acceleration force can be opposed through the shoe onto surfaces of the foot other than the plantar surface, and the situation is undefined.

It is concluded that the effect is due to the distortions of the bony structures during the process of loading the foot. The magnitude of the positional discrepancy may therefore be dependent on the flexibility of the foot, and on the support offered in the shoe, and could not be estimated accurately in advance.

The conclusions of this study are

- that a pressure method must be used to locate the metatarsal heads with accuracy
- that interpretation skills are needed to associate the peaks in the pressure maps with individual metatarsal heads
- that further work is needed to generate a consistent quantitative policy for placing of metatarsal domes with respect to bony landmarks.

This work has been published in part in Lord, Hosein and Williams 1992.

III. Pressure Relief From Moulded Inserts

Background

In the Diabetic Foot Centre at King's College Hospital, a number of patients are treated who require custom orthopaedic footwear. One of the primary objectives of such footwear is to provide a redistribution of plantar pressure such that areas at risk of ulceration will not be overloaded. This may be approached by the provision of a moulded shoe insert, which is formed against an impression of the foot shape. A sandwich construction of low density plastazote^R, PPT^R and high density plastazote is employed for the insert for resilience and durability.. The inserts are considered to be effective for a number of reasons. The contoured shape leads to contact over a larger area than normal with a flat insole, particularly in the midfoot. This both reduces the average pressure and tends to shift the load posteriorly off the frequently problematic area under the metatarsal heads. The material of the inserts tend to mould further to the foot during use, which accentuates the contouring in a way which is responsive to the loads during walking. Peaks of loading are known to occur where the natural fatty pad is reduced under bony prominences, and the compliant layer of the insert will also assist to diffuse the load locally and thus reduce the peak pressures.

The provision of a moulded insole requires an impression or cast of the foot, and its fabrication is time-consuming and costly. The *question* of which patients require this management, and its effectiveness, has always proved difficult to *answer*. Because of the recent development of in-shoe measuring systems, it is now possible to quantify to what extent such orthoses meet their aim of pressure redistribution.

The objective of this short study is to demonstrate and evaluate plantar pressure redistribution resulting from moulded inserts for orthopaedic footwear

Methods

10 patients were identified from those attending the Diabetic Foot Centre by the Orthotist (C Morris of Gilbert & Mellish Ltd) in conjunction with the Medical Officer. The selection criteria are

- orthopaedic shoes with moulded inserts are normally supplied for this pt.
- the patient's foot does not suffer gross deformity (eg. ray amputation)
- patient is not more than moderately disabled in gait
- the condition of the feet is stable (ie no recent surgery, major skin lesion)

Informed consent was obtained to participation in the trial. In view of the non-invasive nature and the short time commitment, verbal consent was considered adequate. The patient was accepted onto the trial when a new pair of inserts has just been provided. Also insoles not made to a mould but of equivalent thickness were provided for their shoes for the purpose of comparison.

The F-scan pressure measuring system was used in this trial, as described previously. In each trial walk, the pressure-measuring insole was inserted between the patient's foot (wearing normal hosiery) and shoe. The patient was then asked to walk approximately 10 m along a straight walkway, repeated twice. The pressure recordings during the central part of these walks were captured on computer. This protocol was carried out with the flat insoles, then the new moulded insoles in place.

Results and Analysis

The results were analysed by noting the maximum values of peaks of pressure occurring in the region of the metatarsal heads during the push-off phase of gait. These were mostly in the 1st and 3rd metatarsal head regions, although peaks under the 2nd and 4th heads were also noted. The peak pressure was averaged over a 15 mm x 15 mm square area (3 by 3 transducer elements) and a comparison of the values at the same locations made for the PPT versus the contoured insert.

The recordings from 3 subjects were invalidated because creases in the F-scan insole caused data to drop-out. For 15 pressure areas analysed from the 7 remaining feet, the peaks were significantly reduced by the use of the contoured insert (PPT: mean 320 ± 80 kPa, Moulded: mean 230 ± 66 kPa: $n=15$, $p < 0.001$). Observation of the composite distribution over a single footstep shows that the load is redistributed into the midfoot area as expected, figure 3.19.

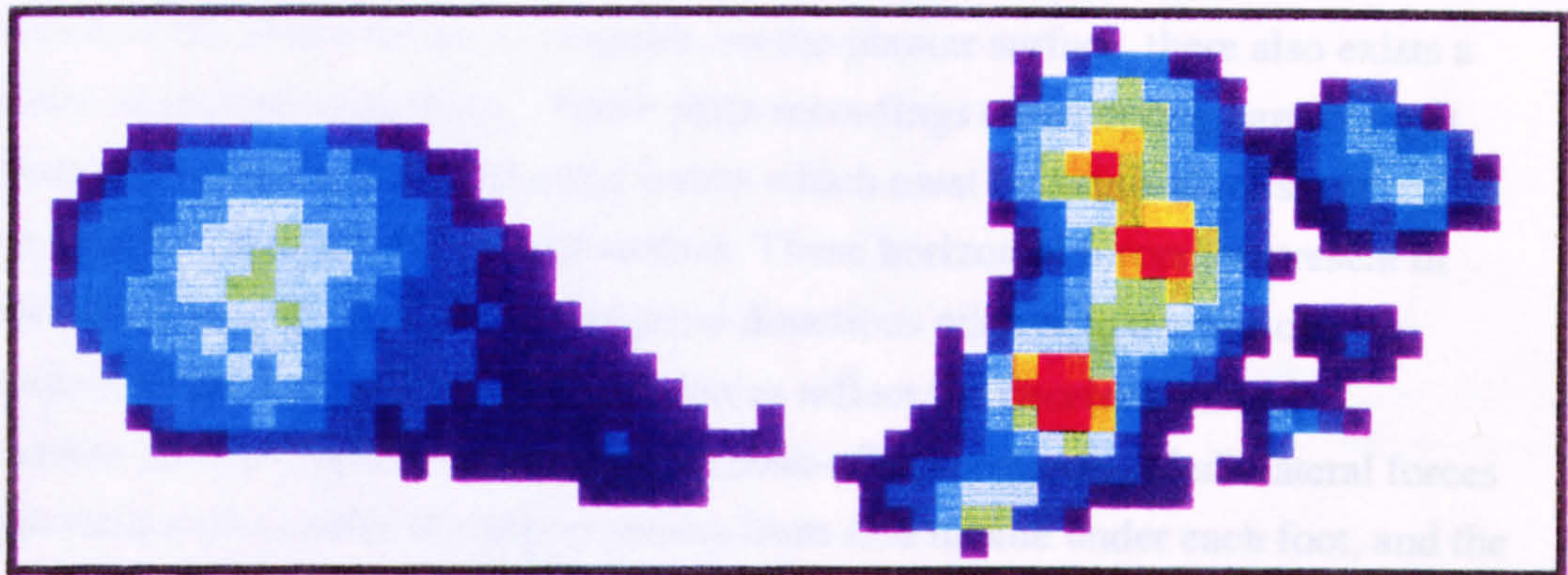
Discussion

The study has demonstrated for the first time the quantitative reduction of peak pressure which has been achieved by the use of moulded inserts. The benefit of these inserts has been considered for some time to be appreciable by the orthotist. This is the first quantitative demonstration of their effect.

This work was presented at the VII World Congress of the International Society of Prosthetics and Orthotics, Chicago, 1992, by Lord, Hosein and Morris.

F-SCAN PEAK FORCE

Stance: 1.12 - 1.96 s



Key (kPa):



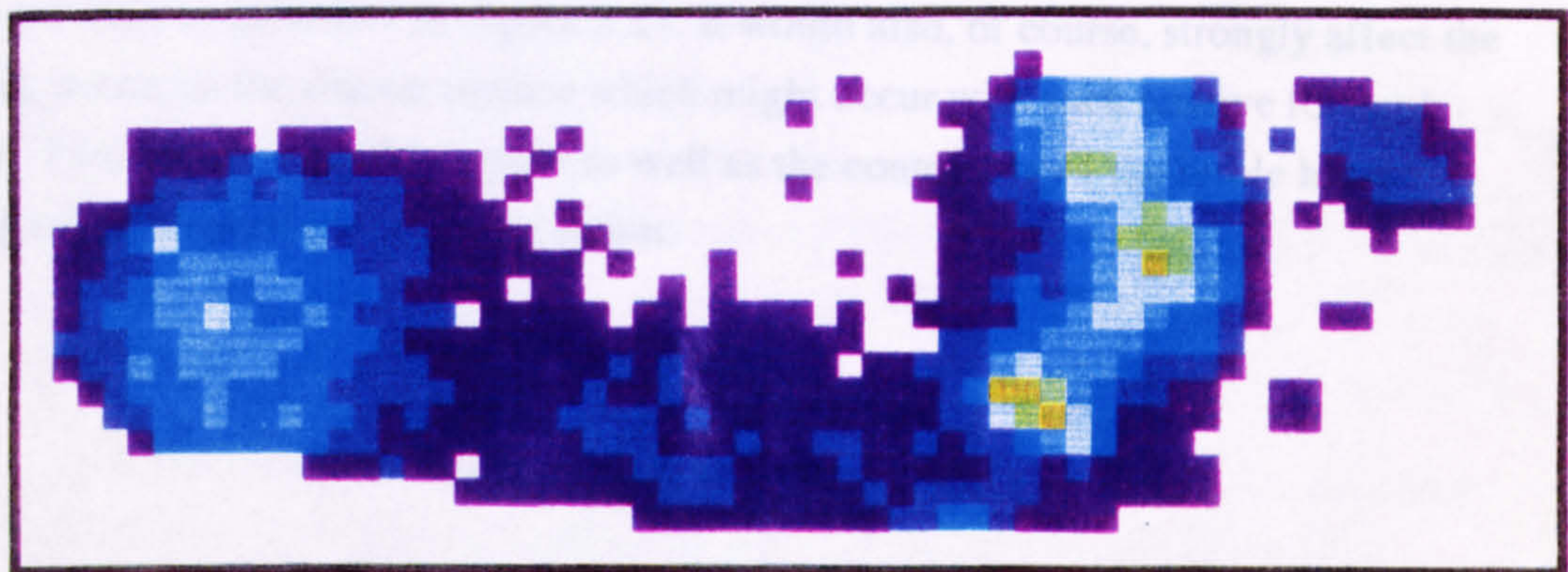
Trial A

Recorded 10:57, on 10/29/91

File: dfchhc

F-SCAN PEAK FORCE

Stance: 2.06 - 2.84 s



Key (kPa):



Trial B

Recorded 11:01, on 10/29/91

File: dfchhd

Figure 3.19 Pressure Distribution into the midfoot area on an example subject

3.5 THE ROLE OF PLANTAR SHEAR STRESS

In addition to the direct stress, or pressure, on the plantar surface, there also exists a tangential stress known as shear. Force plate recordings taken during barefoot gait demonstrate the presence of horizontal forces which must be the result of shear between the flat plate and the plantar surface. These horizontal forces are present in both the anteroposterior and the mediolateral directions relative to the line of progression of the body. The fore and aft forces reflect the deceleration and acceleration phases of gait at heel strike and push-off respectively. Mediolateral forces are generated as the centre of support moves from side to side under each foot, and the body's centre of mass sways laterally during the gait cycle. The horizontal forces must be the cumulative result of shearing at the plantar surface when walking barefoot on a flat surface.

In shod gait, the situation is very different. The horizontal forces now occur between the shoe sole and the flat floor. However these forces can be transmitted to the foot both at the plantar surface and by the shoe upper, figure 3.20 and 3.21. In orthopaedic shoe design, it is often asserted that a high lace-up design is necessary so that the foot is held back in the shoe by pressure on the instep. This design prevents the foot moving forward in the shoe at the deceleration phase, when the horizontal force would be translated into a potentially damaging normal force on the forefoot and/or toe area as indicated in figure 3.21. It would also, of course, strongly affect the shearing action on the plantar surface which might occur with such relative forward motion. Thus the design of the upper as well as the contouring of the insole has a bearing on the presence of shearing action.

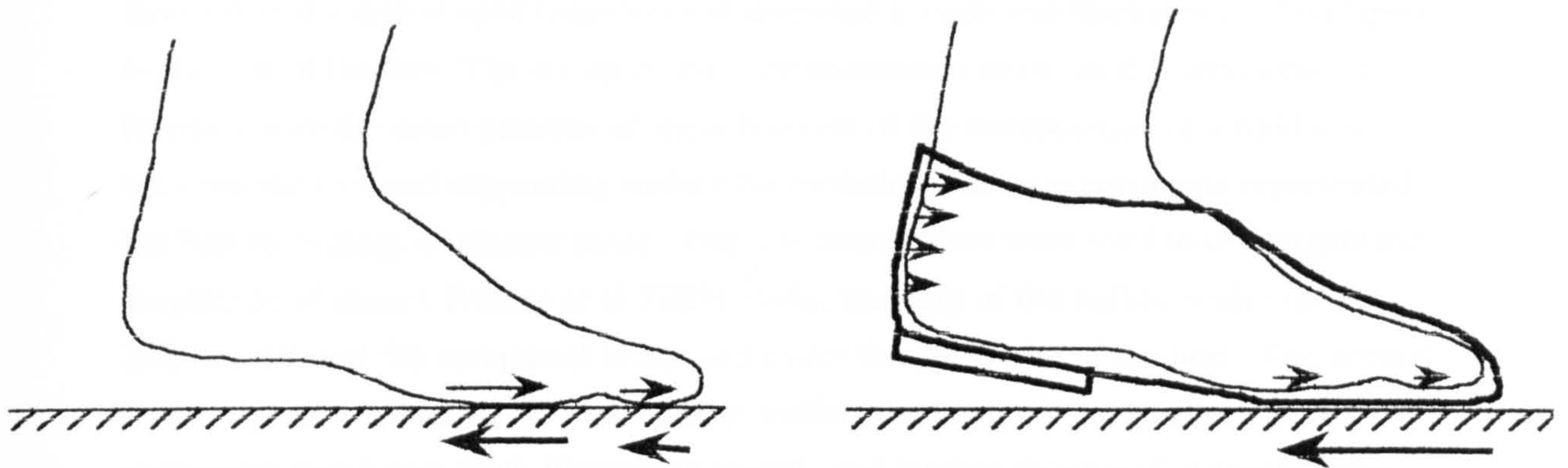


Figure 3.20. Horizontal forces on the shod and unshod foot at the push-off phase of gait: the shear forces on the unshod foot may be reduced by normal forces from the backpart of the shoe acting on the heel.

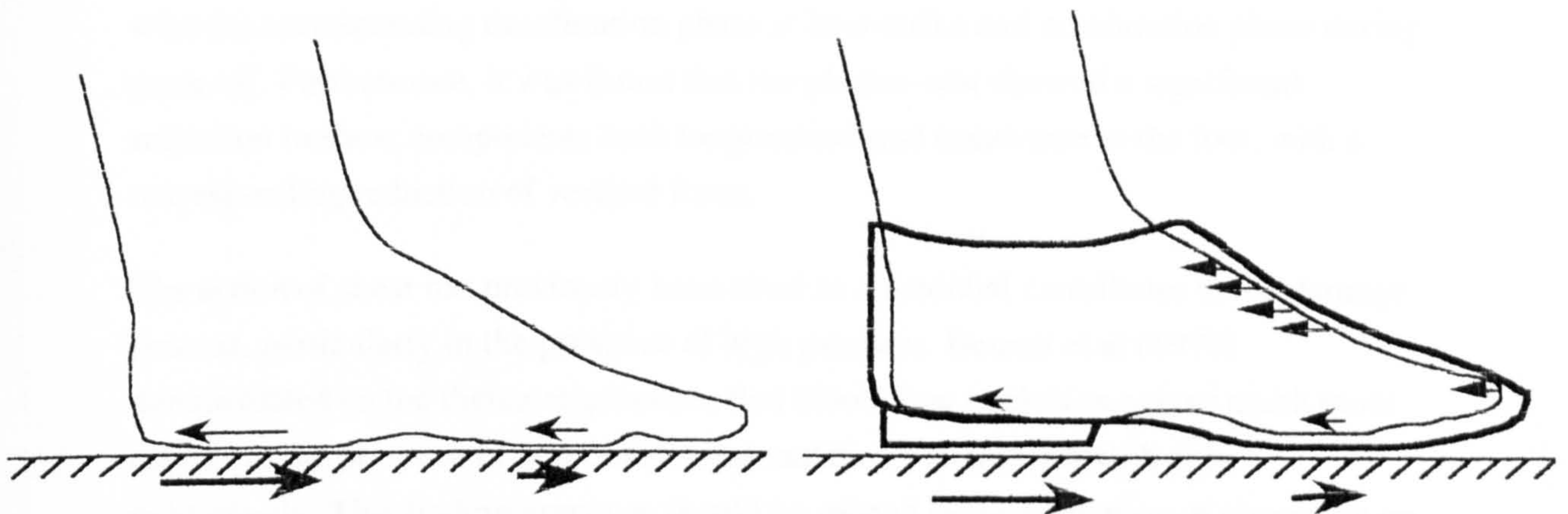


Figure 3.21. Horizontal forces in the deceleration (heelstrike) phase of gait: the shear forces on the unshod foot may be reduced by forces from the forepart of the shoe upper acting on the instep, toe and (not shown) joint area .

Furthermore, contouring of the shoe insole can permit horizontal forces to be partially translated into normal forces on an inclined plantar surface. The placement of a metatarsal dome could, for example, result in the shear stresses under the metatarsal region being converted in part to direct pressure horizontally on the dome.

Little is known of the distribution of shear due to the lack of instrumentation for its measurement. Fairly recent development of instrumentation by Tappin et al, 1980 have utilised a disc-shaped transducer of diameter 16 mm and thickness 2.3 mm taped to the sole of the foot. The set-up of the instrumentation must by this arrangement interfere with the usual patterns of shear because of the interposition of a rigid disc between the foot and supporting surface. Nevertheless, these experiments represented the first recordings of plantar shear. The disc transducers were used to investigate the magnitude of shear (Pollard et al 1983) under the pulp of the hallux, under the 1st, 2nd/3rd, 4th and 5th metatarsal heads and under the mid-point of the heel. Ten normal male subjects were tested in conventional leather shoes, a post-surgical plastic shoe containing two 6 mm thick Plastozote inserts, and leather shoes with a single 6 mm insert. Some experiments were also conducted in below-knee plaster casts with rocker bottom ('walking casts'), and also in surgical shoes with a rockered sole (similar in shape in the forefoot to the sole of a clog). These early experiments indicated that a forward shear was present (acting on the transducer) under the heel at heel strike and also under the lateral metatarsal heads, and a backward shear under the central and medial forefoot at push-off: the latter peaked at the time of maximum vertical pressure (Tappin & Robertson, 1991). The findings are stated as compatible with the corresponding deceleration phase at heel-strike and acceleration phase during push-off. Furthermore, it was found that the plaster-cast showed a significant reduction in shear components both longitudinal and transverse to the foot, with a corresponding reduction of vertical force.

The action of shear has previously been cited as a potential contributor to the damage process, particularly in the presence of high pressure. Bennet et al (1979) demonstrated on the thenar eminence that blood flow occlusion occurs much more rapidly in the presence of combined shear and direct stress than with either individually. This finding however should be related to the formation of ulceration on the plantar surface with great care. Unlike the formation of decubitus ulcers (bedsores) where prolonged occlusion of blood flow is considered a primary cause of tissue necrosis (eg. Bader 1990), there is no evidence to suggest this mechanism in the formation of plantar ulceration. Particularly, it must be noted that the average pressure under the foot in standing is of the order of 20-30 kPa: bloodflow occlusion would occur at values an order of magnitude lower, demonstrating that this is the normal condition under the loaded parts of the plantar surface. Other more direct mechanical damage mechanisms must be propose in this case.

It is suggested by clinicians, from their own observations of presenting ulcers, that some ulcers initiate deep in the soft tissue perhaps at the interface of the soft tissue and

a bone surface, with considerable damage being done before the lesion becomes apparent at the surface. Tissue deformation resulting from even low shearing forces may contribute to generation of high stresses deep in the soft tissue. The presence of gradients of direct pressure are also contributory to shear in the deep tissues. The biomechanical analysis of such a situation is as yet very unclear.

It has also been suggested that some ulcers may form as a plug of callus, which when subjected to repeated torsion gradually dislocates. A gradient of shear can be expected where torsion occurs. Consider the forefoot at the push-off phase of gait. It is wholly possible that the foot twists at this point in some subjects, giving rise to a gradient of shear across the width, figure 3.22 It is noted that the direction of shear at a particular location may not even reflect the direction of the integrated shear stress for the whole foot in this instance. Indeed, the work previously cited by Pollard et al (1983) would support the presence of this pattern of shear, with a change of direction of the longitudinal shear across the metatarsal heads.

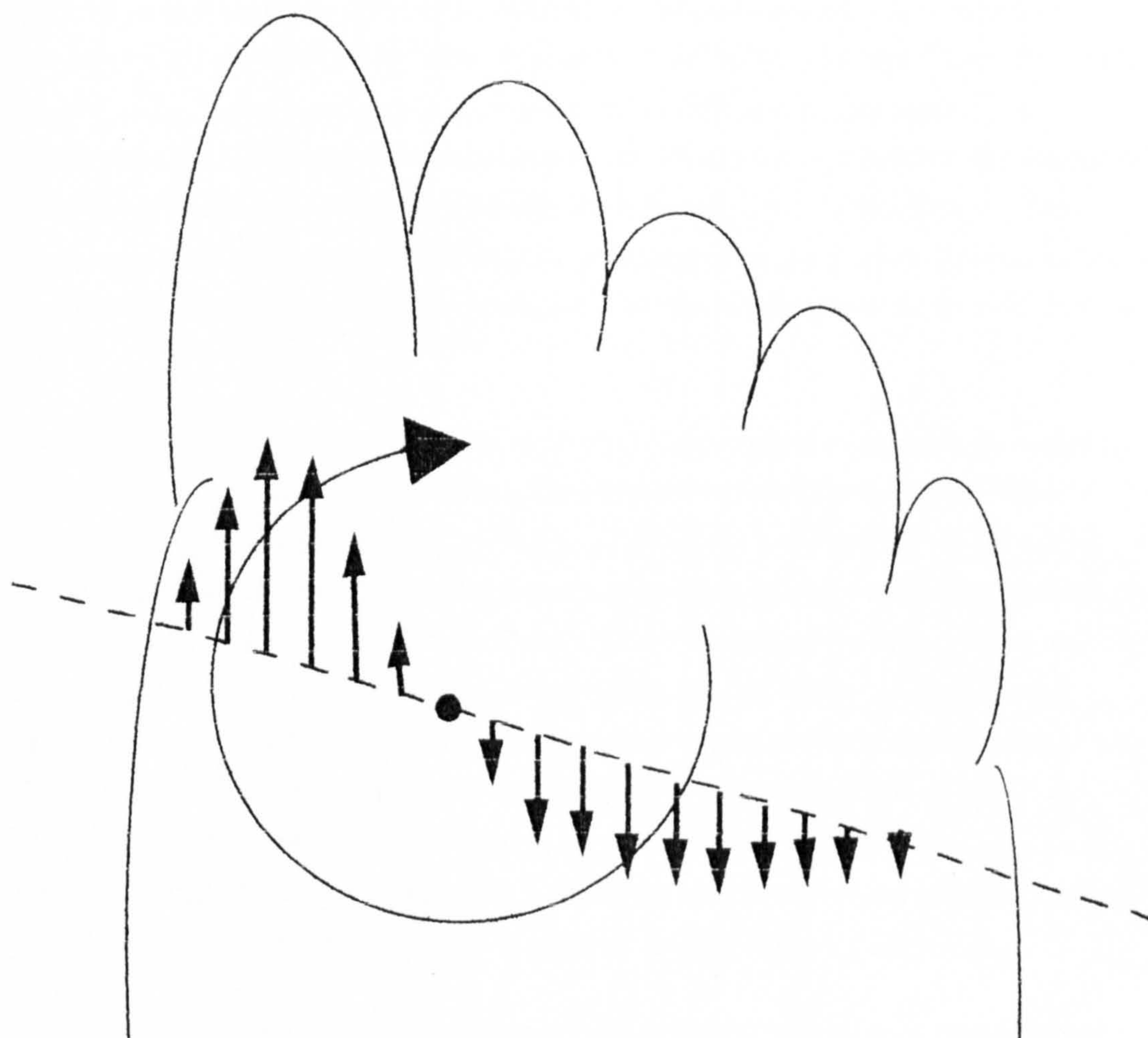


Figure 3.22 Torsion would result in a gradient of surface shear along a profile such as that shown along the metatarsal break; mediolateral shear component not shown.

Work initiated

Work has been initiated as a separate PhD project under the supervision of the author to map the presence of shear and to investigate its causative relationship to plantar ulceration particularly related to the formation of diabetic neuropathic ulceration. This work uses a discrete shear transducer developed recently by Porter & Williams(1991) in the Department of Medical Engineering & Physics at King's College School of Medicine and Dentistry. This transducer is based on the design of Tappin at Middlesex Hospital, and has been extended to be bi-axial. The work in progress concentrates on experimental quantification of shear stress under the shod foot of both a normal and diabetic population, embedding the transducers into an insole in order to minimise the measurement errors. Following the work of described above in the location of transducers, the F-scan system is also used to gain a consistent placement. Preliminary findings of this work are reported in Lord et al (1992).

3.6 CONCLUSION

Over the past two decades, many techniques for measurement of pressure under the feet have been evolved, resulting now in numerous publications giving data on normal and pathological cases. It has been noted by other authors that the results of these studies are often difficult to compare or show results which do not support each other. In this chapter, spatial resolution and thresholding have been considered as factors which need to be taken into account, and their requirements have been evaluated experimentally. Three case studies are cited, where special attention has been paid to these factors in obtaining a reliable measure.

It has been demonstrated that accurate assessment of peak pressures under the plantar aspect of the metatarsal heads may require a measurement technique with load cells of typically less than 2 mm by 2 mm. Many of the values quoted in the literature for peak pressures under the plantar metatarsal heads will be underestimated. This may account in part for lack of comparability between results of different techniques. The pedobarograph is the only instrument at present which can provide an adequate spatial resolution for accurate profiling although other factors limit its absolute accuracy. Because of the significant spatial filtering occurring with most other devices, values of 'peak pressure' must be qualified, particularly by the statement of the area of each load cell.

Many of the measures which have been quoted in pressure studies have been shown to be highly sensitive to threshold effects. This is most notable for the area, which is highly dependent on the threshold of the measuring device. Thus claims for certain insert designs to increase the contact area must be qualified by a careful quantification of threshold of the measurement system. Apparent weight of the subject may also vary with the threshold, and this can lead to erroneous results where, as often for the pedobarogram, a comparison of the integration of pressure with the patient's known weight is used to calibrate the pressure readings. It also accounts for an apparent 'absorption' of bodyweight by the use of inserts (known as the 'levitation' effect, which is increasing being reported by colleagues with in-shoe measuring systems in support of the erroneous theory that contoured inserts 'absorb' foot loading).

Using the pedobarograph and a graphical inspection programme, a study has been undertaken of the relationship of callus formation to peak pressures in the diabetic neuropathic foot. The clinical significance to the routine chiropodial treatment of the

foot is outside the scope of the current study. It does, however serve to illustrate that peak pressures can be altered by local skin conditions such as callus debridement. The presence of callus results in a very localised high pressure peak which would not be accurately detected by any of the matrix insole systems at present on the market because of their limited spatial resolution.

The implications of these studies to the utilisation of pressure measurement for insert design are that a degree of caution would be wise in quoting absolute values. It has been demonstrated that peak values are affected by the resolution of the current available equipment, and even can be significantly altered by chiropodial debridement of callous. Because of the characteristics of the pressure distribution, small changes in threshold of measuring equipment can severely alter the apparent contact areas measured: where an insert is designed to increase the area of contact, then threshold effect must be taken into account. The last case study using the F-Scan device was an example where this effect could be very misleading. However, providing that the user is aware of any non-ideal characteristics of his measuring device, very valuable information is gained from pressure measurement. The case study of location of high pressures in the metatarsal region demonstrated how the usual method of palpation often leads to significant error in position, where the metatarsal heads locations are used as a guide for the positioning of, for example, metatarsal domes. Then it is necessary to use pressure measurement for this purpose.

Finally, the influence of shear stresses are very little understood at this time, and these are probably highly dependent on both the contouring of the shoe insert and the upper design. Further work has been initiated in the form of a new PhD study which aims to quantify the presence of plantar shear in normal and pathological cases. Such quantitative measurements will, no doubt, in future provide design data for integration into CAD/CAM design systems.

Acknowledgements

These case studies were supported in part by the Moorgate Trust Fund. Riad Hosein, postgraduate student, contributed by collecting the F-scan recordings in the clinic and assisting with the pedobarograph data collection. Chris Morris, orthotist from Gilbert and Mellish Ltd, is thanked for his assistance in the protocol development and identification of suitable patients for the moulded insert study. Steve West, postgraduate student, produced the photographic paper which was used as the pedobarograph foil, and assisted with its calibration. The work with Diabetic patients was undertaken with the assistance of Alethea Foster, chiropodist in charge of the diabetic foot centre, and under the medical supervision of consultant diabetician Dr Michael Edmonds.

CHAPTER 4. INSERT DESIGN - RIGID ORTHOSES FOR HINDFOOT CONTROL

4.1 BACKGROUND

Basic Types of Inserts

Shoe inserts can be provided for several different purposes. These purposes can be considered under two general categories

pressure relief

functional alignment

The pressure relieving inserts have been touched on in the previous chapters. Where the plantar skin cannot sustain the local pressure, either because it is excessive due to loss of padding, or because the skin is pathologically intolerant of normal stress levels, then there is a simple requirement to relieve the level of stress. From the earlier work of chapter 3, it is appreciated that the normal pressure distribution under the foot is often far from even, with peak pressures even in standing often at least 5 times greater (up to 150 kPa) than the average pressure(approx. 30 kPa) . With pathology, the peak pressures are often an order of magnitude greater than the average. Thus there is usually a wide scope for reducing peak pressures by a process of redistribution over the available plantar surface. There may also be scope for increasing the contact area, especially in the case of cavus (high-arched) feet where the midfoot is not in contact with a flat supporting surface.

It is possible to approach the solution by spreading a sharp peak of pressure through the use of a cushioning insert. Two conflicting factors limit the effectiveness of this approach. If the cushioning material is too soft, a bony protuberance such as a prominent metatarsal head will 'bottom out' through the limited depth of the insert material that the shoe can accommodate. If the material is too hard, then the spatial smoothing is insufficient to spread and reduce the peak pressures adequately. This problem is often ameliorated by using a sandwich construction, so that the soft upper layer is backed by a stiffer under layer to prevent the protuberance hitting the hard shoe insole. This may however not be sufficient.

An alternative and complementary approach is transfer the load to another part of the plantar surface. This requires the use of a shaped or moulded insert, where a build-up

of material under one part of the foot ensures that the load is borne more in this locality. Typically, an instep raise can be used to transfer load from the forefoot into the midfoot, as demonstrated in the case study of moulded inserts.

Although the emphasis to date has been on designs which relieve pressure at the skin interface, shear stress may also be implicated in tissue damage. As discussed in 3.5, shear stress distribution is as yet ill-defined by quantitative study. Some insert materials are however claimed to reduce shear stress by allowing for a tangential motion between their upper and lower surfaces. In this context it is also noted that the so-called anti-friction socks constructed from a double skin might also reduce surface shear levels. A distinction is drawn between shear stresses, and friction. In the latter case, relative motion is occurring because the ratio of shear stress to normal stress is greater than the coefficient of friction between the two respective surfaces. Friction is known rapidly to cause skin lesions by its rubbing action. Shear has not yet been investigated to establish its deleterious effects. It might be anticipated that the highest shear occurs in areas of high direct pressure, and it may be difficult in this case to isolate the effects of pressure from shear.

The other main category of inserts, and that to be investigated in this chapter, is **functional orthoses**. Functional orthoses are so called because they are intended to alter the basic function of the foot in gait. This is achieved by alteration of the alignment of the skeletal structure of the foot. There are of course consequent changes in the plantar stress distribution.

Orthoses for hindfoot control are the most common in this class. The hindfoot normally moves into a valgus orientation at the heel strike of the gait cycle, and rotates by subtalar inversion into a varus position at the push-off phase. This process is necessary to achieve the correct orientation of the midfoot joints at push-off; mechanical locking in this orientation is necessary to provide a rigid lever to allow the push-off action from the forefoot. Where the hindfoot collapses into excessive valgus condition (eversion), then this operation is hindered. The resultant abnormal function puts a strain not only on the foot but also on the knee because of the linkage between subtalar motion and rotation of the tibia. The role of the orthosis is to prevent excessive eversion. The orthosis is constructed over a modified plaster cast of the plantar surface of the foot, and made of a semi-rigid plastic. The heel is 'posted' (wedged) to tilt the hindfoot out of excessive valgus.

Shape vs. Pressure Distribution

In the practical design of pressure relieving inserts, prime consideration is given to pressure redistribution, whereas in the design of functional orthoses more emphasis is placed to the shape of the orthosis. In reality, pressure and shape are inextricably linked. Any alteration in the pressure distribution must be accompanied by a change in the shape of the plantar surface of the foot, and vice versa. The difference between the two types of insert is that in the first, the designs are constructed to achieve a pressure effect, with the shapes and functional consequence of less consequence, whereas in the second, the design must maintain a given shape (orientation) and function where the pressures adjust to provide the forces necessary to achieve this objective.

The relationship between shape and pressure at the interface is a function of the shape and material properties of the foot, in addition to those of the insert. This makes it impossible to construct hard-and-fast rules about the insert design in isolation from measurements of the individual foot properties. However it would be useful, especially in the context of CAD/CAM, to define the average and ranges of behaviour of the foot for this purpose, so that a general algorithm can be developed. It would then be possible to consider exactly which measures need to be taken for an individual foot in order to tailor the design.

Objective of this Study

This study considers a single example of the quantitative measures of foot behaviour which can provide the basis of a CAD/CAM design system. The chosen example relates to the shape modifications which should be made to post a hindfoot control orthosis.

Although an individual foot has a characteristic form, its exact shape can vary considerably with the skeletal articulations and distortion in parts of the soft tissues. When a plaster of Paris impression is made of the foot for purposes of subsequent customised shoe insert or shoe last manufacture, the foot is deliberately placed in a particular orientation and loading condition. The choice of the condition is partially determined by the clinical objectives, but also partly the result of a particular preference by the individual orthotist and his/her training. The surface contours of the resultant casts are markedly different depending on the method selected. Yet many different casting methods can lead to successful orthoses or shoes. One interpretation of this observation is that the wearer is fairly insensitive to the contours of the orthoses. Another possible explanation lies in the subsequent modification of the casts, which may compensate for each different technique to give a comparable finished product.

Since the cast shape and the subsequent modifications are not quantified in any exact terms, the true explanation remains a debatable issue.

Furthermore, the corrections applied either by external loading at the casting stage or subsequent modifications to the cast cannot be described with accuracy, particularly in association with the underlying biomechanics of the limb. This is particularly relevant when attempts are made to imitate the craft process of orthosis/shoe manufacture by a computer-aided system.

Fundamentally, changes in orientation and external loading result in displacements of the underlying skeletal articulations and redistribution of the soft tissues. Study of the external foot shape may be able to yield information about the biomechanics of these processes. So far this approach has not been explored for the foot, although similar objectives have been studied in a parallel field: the deduction of spinal mechanics from surface contours of the back has received considerable attention (Turner-Smith & Harris, 1985) particularly to provide a non-invasive method of scoliosis screening. The axial twist of the spine has been investigated by quantification of the surface contours at a number of transverse sections down the spine .

In the process of manufacture of a rigid or semi-rigid orthosis for control of hind-foot angulation, the foot is typically cast in plaster of Paris not in its free state but in a corrected position. The forefoot is everted (pronated) by external forces, thereby inducing an axial twist of the forefoot relative to the heel. This chapter describes a method to assess the axial twist of the foot induced during this established casting technique, as assessed from the surface contours of the plantar surface. From a plantar contour in a specified transverse plane, a single numerical value for the transverse slope is defined, and the development of this slope along the length of the foot is used as an indicator of axial twist. Since assignment of a single value for slope has an unavoidable arbitrary nature, part of the objective of this research is to seek a satisfactory and reliable method of quantification of plantar surface contours for subsequent investigations.

This investigation of shape corrections has been published in Foulston et al, 1990. The figures are reproduced from that publication by kind permission of the publishers of Clinical Biomechanics. The author designed the experiment, wrote the data acquisition programme, commissioned the instrumentation and analysed the results with the assistance of John Foulston in the clinical aspects of trial design and digitisation, and Steven West in selecting the subjects, preparing the plastercasts and measuring calcaneal tilts.

4.2 METHOD

Casting

The plantar surface of each foot was carefully marked with a water soluble felt tip pen at defined anatomical landmarks of the foot . These are points on the skin overlaying the 1st, 2nd, and 4th metatarsal heads, at the tuberosity of the navicular on the medial side and over the tuberosity of the base of the fifth metatarsal laterally. The centre of the ball of the heel was estimated visually and marked. In addition, a line was drawn bisecting the posterior aspect of the calcaneum.

The subject was placed lying prone on a plinth with the foot hanging freely over one end, figure 4.1. Both the ankle and the subtalar joint (the articulation between talus and calcaneum) were put in their neutral positions ie lateral border of the foot vertical (ankle joint at 90 degrees) and the subtalar joint neither pronated or supinated so that the head of talus could just be palpated (located by touch). Casts were made in two orientations in succession

- forefoot free to rotate relative to the heel in its naturally inverted position, and
- forefoot corrected (everted) by manual pressure onto the head of the 4th/5th metatarsal heads so that the forefoot plane is brought as far as possible parallel with the heel plane and the midtarsal joint is maximally pronated about its oblique and longitudinal axis.

The second position (forefoot corrected) is one of the established methods of casting for rigid insert manufacture (Root et al, 1971), with the foot in the orientation it would normally take in mid-stance phase of gait. Positive casts were produced from the shells with the anatomical landmarks transferring through. The thumb depression in the corrected casts in the 4th/5th metatarsal head region was filled as normal practice for such casts. From the transferred anatomical landmarks, seven markers were defined as reference points. Four of these coincided with the landmarks on the metatarsal heads and the midheel, two were assigned at the ends of the calcaneal bisector line, and a midfoot point was determined at the intersection of the midline of the foot with the line joining the landmarks over the lateral and medial tuberosities.

Measurement from the Casts

Certain linear measures were taken between markers on the casts for comparison with the digitised equivalents, as a check on accuracy. Also an assessment was made of forefoot rotation referenced to the heel by two separate clinically-accepted techniques. The first method utilises the calcaneal bisector: the cast is allowed to rest on a flat horizontal surface, and a tractograph is used to measure the angle between the bisector and vertical in the transverse plane. Another method used a graduated gravity angle finder, which relies on the casts being filled when the calcaneal bisector is balanced to the vertical: the angle finder is then placed onto the superior surface of the cast across the forefoot.

The casts were measured at random by a clinician who did not have access to other results, with a period of 5 days between each method employed.

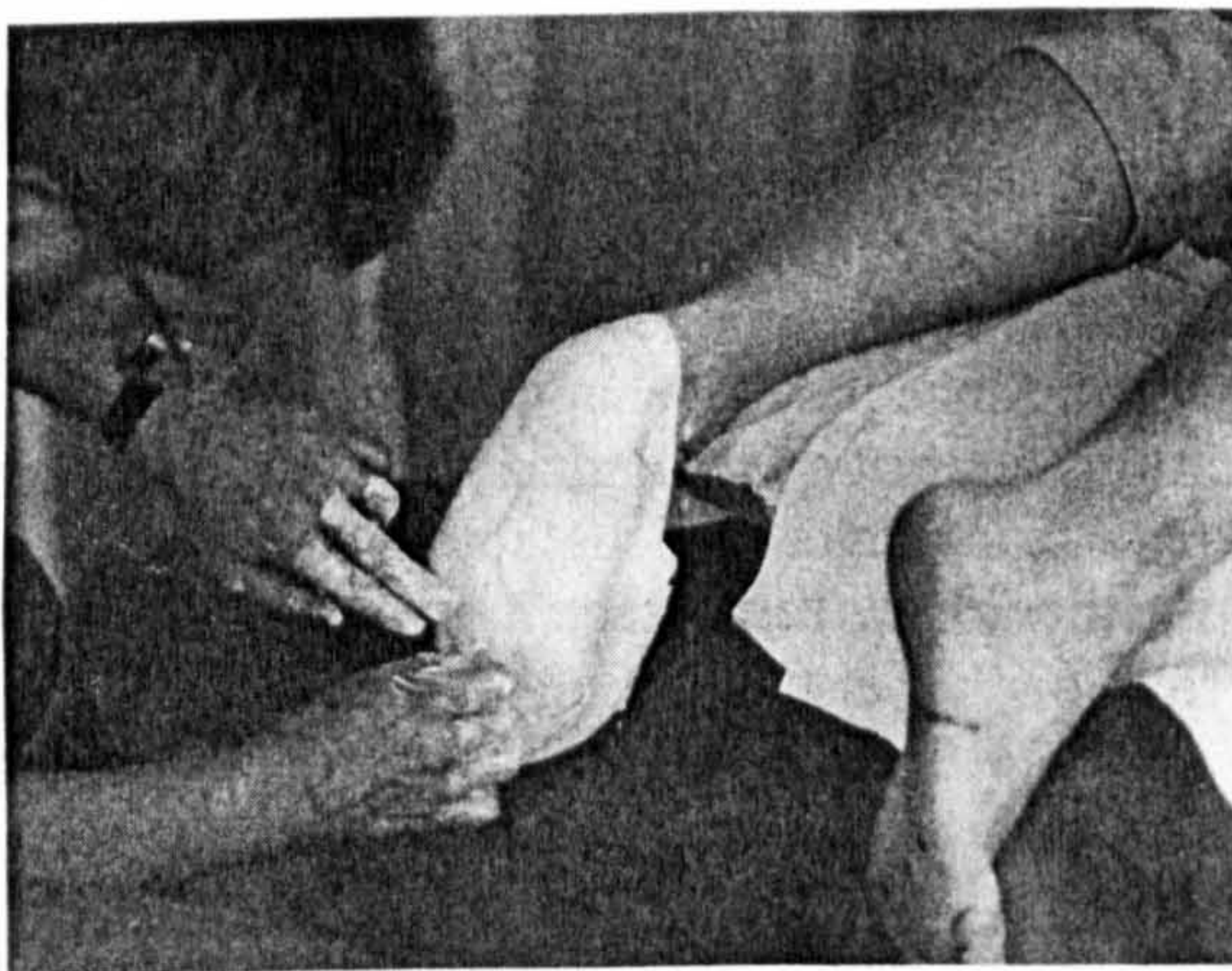


Figure 4.1 Patient in casting position

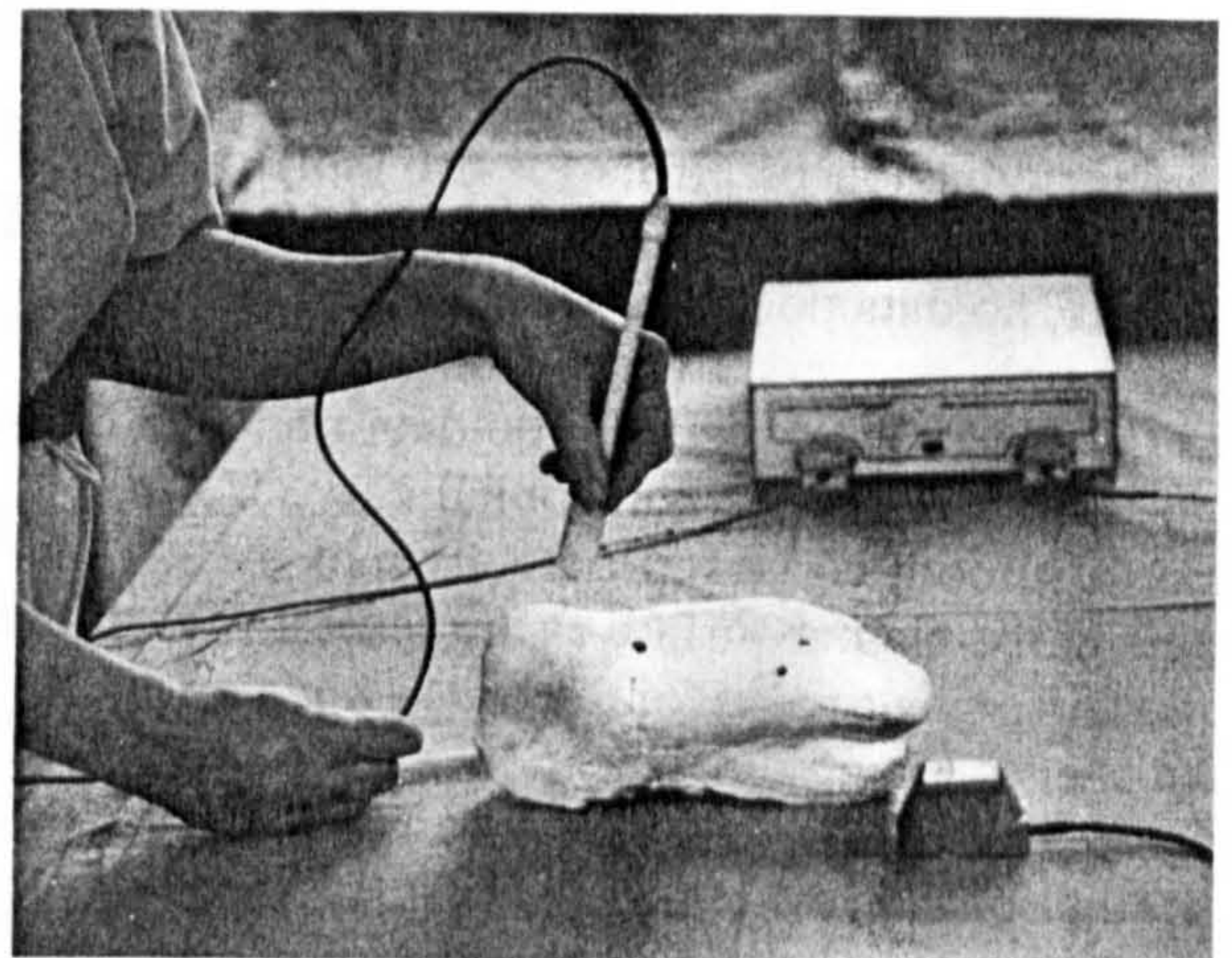


Figure 4.2 The Isotrak equipment

The System for Surface Data Capture

The plantar surfaces of the positive casts were digitised using a 3Space Isotrak¹, figure 4.2. The Isotrak is an electro-magnetic device and consists of a source module, a sensor and a microprocessor controller. The source emits magnetic radiation which the sensor, optionally a hand-held stylus, detects. These signals are transmitted down a wire to the controller where the position of the sensor's tip in 3 dimensional space is deduced. For our use, the controller is then linked to a personal computer (an Apple Macintosh Plus 1/20) which sets the mode of data acquisition - single point, free streaming or incrementally triggered - and stores the coordinates. A similar biomechanical application of the Isotrak has been reported previously by Percy and Hindle, 1989, using a sensor module in place of the stylus.

Acquisition software was written by the author to permit the user to capture surface data from the sole of the cast over the area of interest. The stylus is initially moved to each of the seven markers in turn in response to cues on the computer screen, and seven single data points are captured. After this, the surface is slowly swept with the stylus while the Isotrak captures points in a spatial incremental mode, building up a map of randomly-spaced points over the entire surface. A total of 1000 points including the first seven markers are collected and stored as X-Y-Z coordinates.

Experimentation with the Isotrak was necessary to establish parameters for satisfactory accuracy and spacing of the data set. Static accuracy tests conducted by moving the stylus tip in turn to fixed points on an object of known dimensions and similar size to the foot casts showed that the absolute accuracy is within the quoted 0.03 inch RMS (less than 1 mm) when operated in an averaging mode. This accuracy is independent of the stylus orientation. However dynamic tests conducted by sweeping the stylus over known surface contours with free data streaming at approximately 20 updates/second produced errors an order of magnitude greater. Subsequent tests were carried out by swinging the stylus as a pendulum on strings of different length to obtain a harmonic motion of different frequencies. It was established that the response, in terms of the estimation of the position of the tip, began to be noticeably distorted above 0.1 Hz and at 1 Hz had a magnification factor of greater than 2. Discussion with the equipment's designer at the manufacturers has established that the dynamic response of the device deteriorates above 0.1 Hz due to filtering in the microprocessor. The positional accuracy is particularly sensitive to rapid changes in stylus orientation since the tip coordinates are calculated from the location and orientation of a sensor embedded in the central part of the stylus wand.

¹Polhemus Navigation Sciences Division, McDonnell Douglas Electronics Company, PO Box 560, Colchester, Vermont 05446, USA)

Hand movements during sweeping will have significant signal content above 0.1 Hz especially during orientation changes at the ends of each stroke. The alternative to sweeping, single point capture, was not considered feasible to build up a reasonable surface representation. A compromise was adopted, whereby the transmission of a data point is triggered by movement through a fixed spatial increment; however this data point is not stored if the time from the subsequent point received is less than a threshold value, thereby rejecting points if the apparent motion becomes too rapid. Auditory feedback alerts the operator when points are not being stored.

By trial and error methods spatial increments of 4 mm and timing interval of 0.1 s were adopted. Data capture takes approximately 3 minutes. The results of a digitisation of the surface of a cylinder are shown in figure 4.3, with a representation of the cloud of 1000 points and a thin transverse slice of data taken in the central region. Accuracy of a polynomial curve fitted through the points in the slice is better than 0.5 mm, ie no point lies more than 0.5 mm from the polynomial

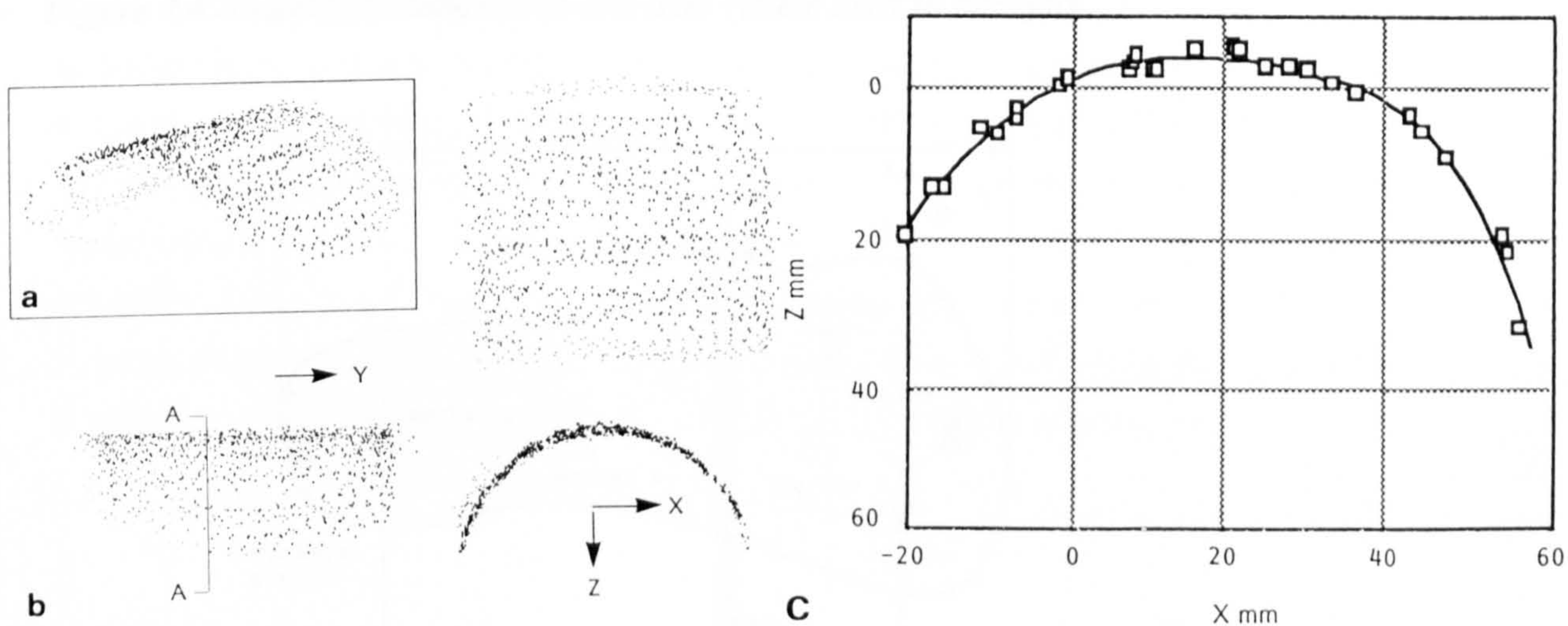


Figure 4.3 a, isometric view and b, views in three planes, of data cloud obtained from the top surface of a horizontal cylinder. c, single slice of data taken from the cloud and fitted with a curve.

The raw data has a random orientation. For purposes of comparison, each set of data was reorientated by reference to the axes defined in figure 4.4. Left foot data are mirror-imaged to conform to a right foot convention. By this method of orientation, the forefoot planes in free and corrected casts are brought into registration and the heels are rotated relative to each other; this is the converse of the functional situation, where the heel remains fixed and the forefoot is rotated.

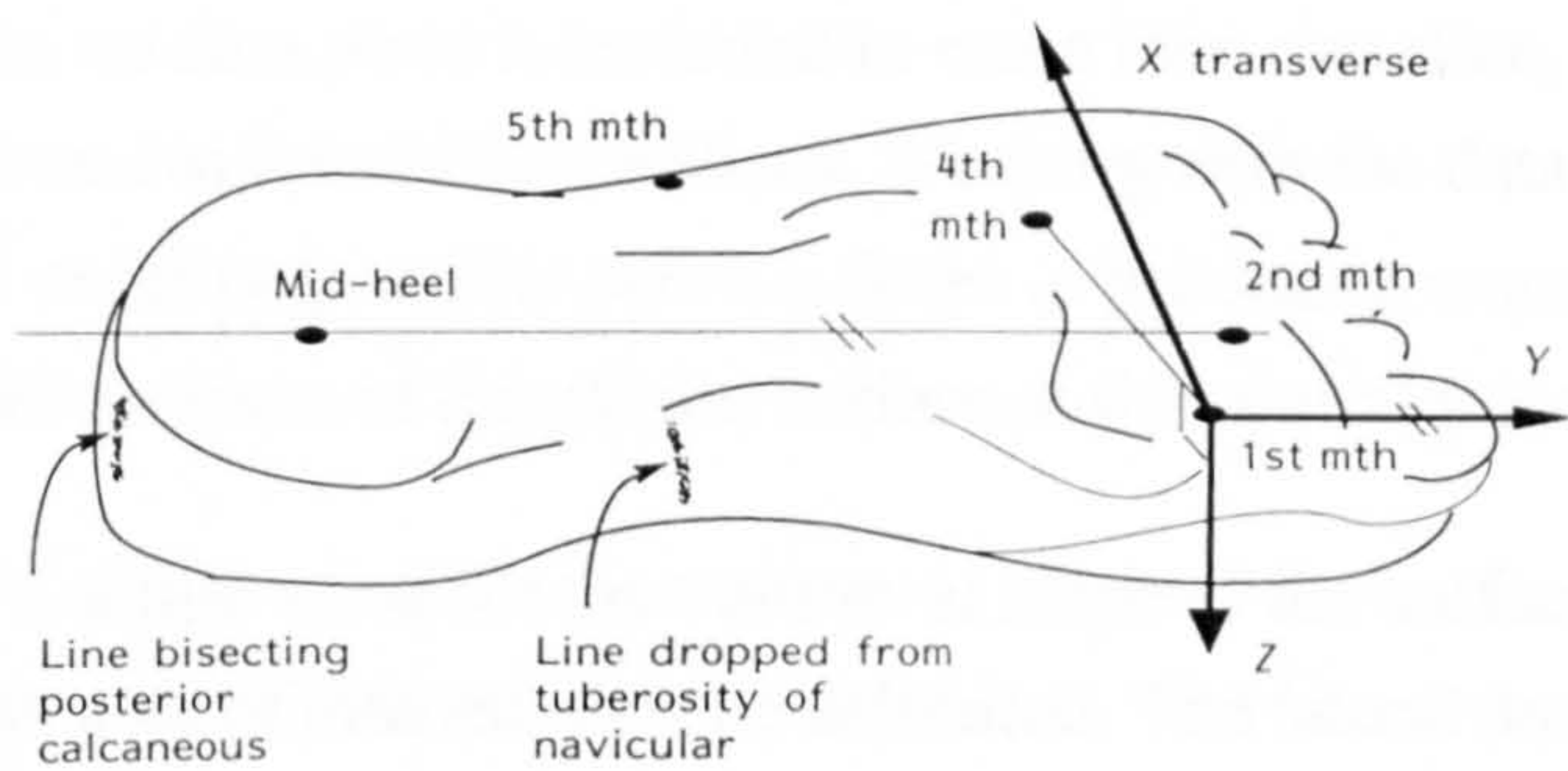


Figure 4.4 Anatomical landmarks and axis system used in analysis

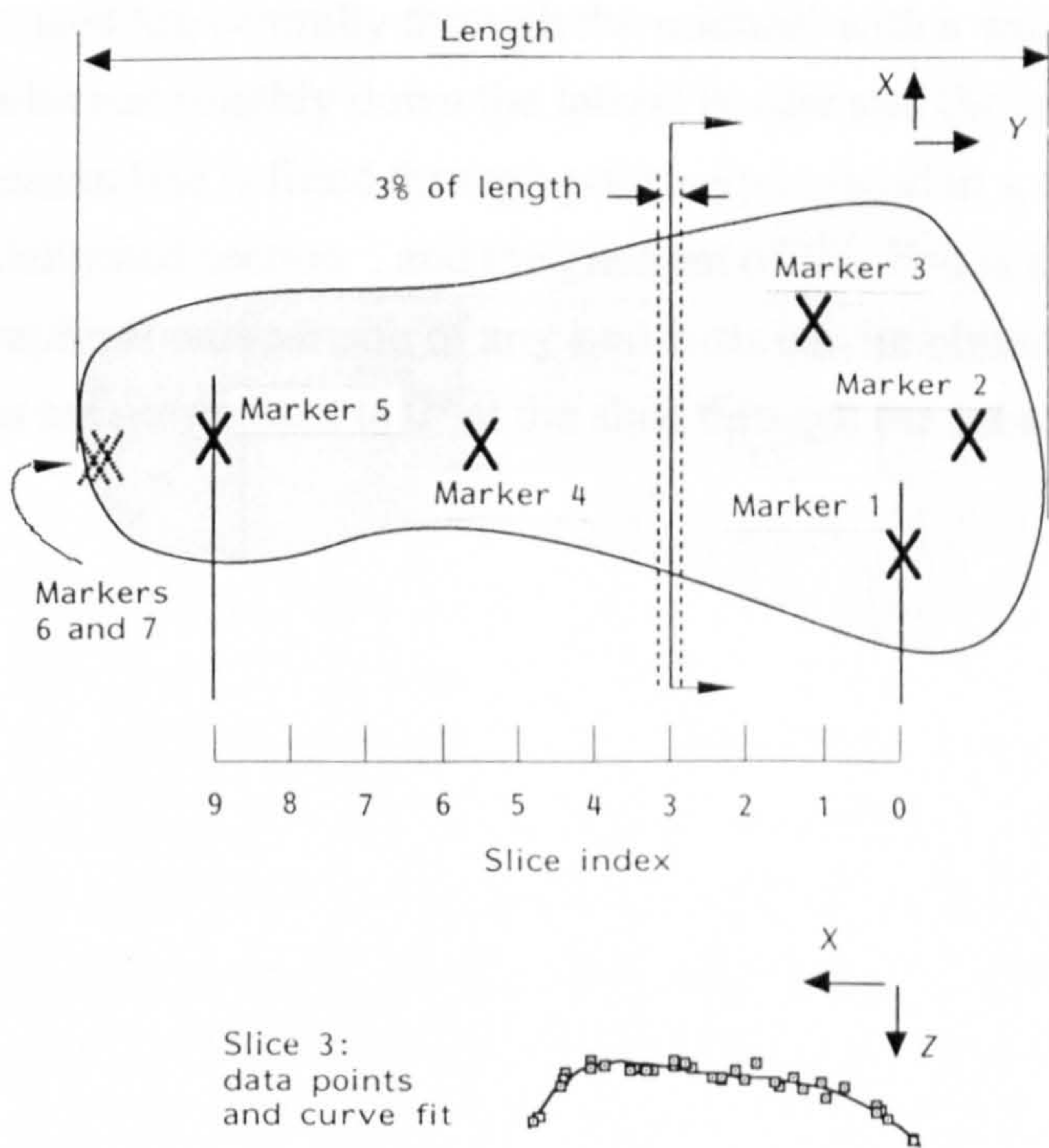


Figure 4.5 Location of data slices relative to marker points and example of a 5th order polynomial fit through one slice of data.

Analysis of Surface Slopes

The transverse slopes are investigated at 10 locations equi-spaced along the length of the sole from marker 1 to marker 5 (figure 4.5). Each location is specified by a central value of the y coordinate. All the data points lying within a narrow slice in the x-z plane, as indicated by the dotted lines in figure 4.5, are extracted from the raw data to represent the surface at this location. Experimentation indicates that a slice width of 3% of the range in the y direction includes sufficient data points without introduction of errors (>1 mm) due to its thickness. Ten slices include approximately 30% of the data points, no data point is included in more than one slice, and only markers 1 and 5 are guaranteed to lie within the slices. Working with the data points in each slice in turn, a 5th order polynomial curve is fitted to produce a smooth curve representative of the original contours of the plantar surface at the central y location.

To obtain a single value for the transverse slope of the surface at each longitudinal location, an area of interest must be delimited. The lateral and medial borders of the sole are not of interest in determining the plane of the forefoot or heel, and clinically the forefoot plane is determined approximately across the metatarsal heads and similarly the heel plane across the midheel area. Therefore the area of interest has been described by a truncated triangle, with its base from the 1st to the 4th metatarsal heads, and its truncated top centrally through the midheel with a width of 40% of the base. The long sides run roughly down the lateral border and the instep. For each slice, a linear regression line is fitted through points equispaced in x on the polynomial curve across the delimited section, and the gradient of this line is taken as the transverse slope. A graphical comparison of any two casts can be obtained, figure 4.6, where the slope angles are normalised to 0° at the slice through the 1st metatarsal head.

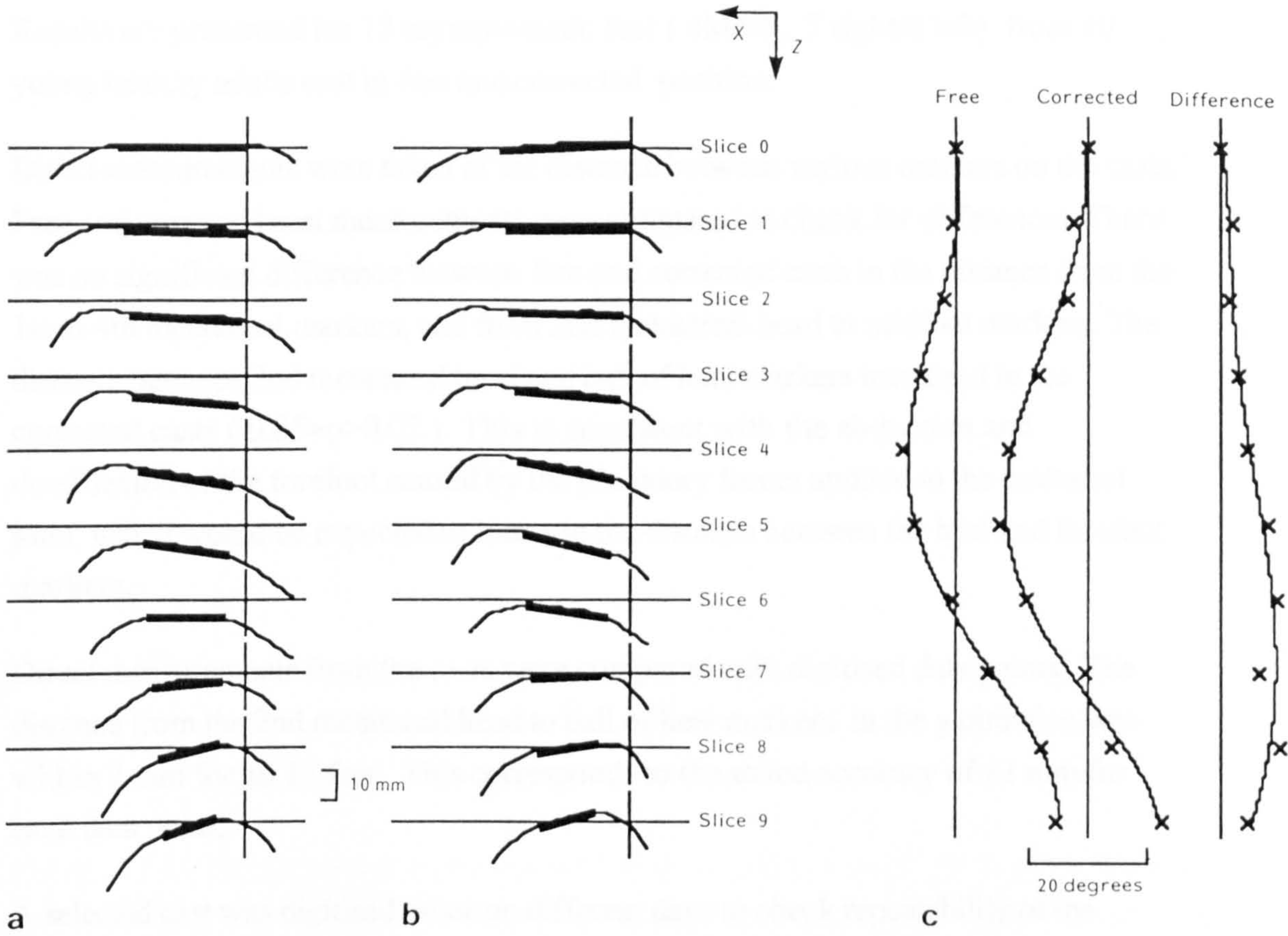


Figure 4.6 Slopes determined for subject H at the 10 selected locations along the foot in (a) free, and (b) corrected, orientations. (c) Plot of slopes normalised to zero at the forefoot.

4.3 RESULTS

Results are presented for 13 asymptomatic feet (4M/9F, 7 right/6 left) from 10 young healthy adults cast in free and corrected position.

Direct measurements were taken of the distance between various markers on the casts. Free and corrected cast measurements were compared to check for differences. There was no significant difference between free and corrected casts in the distance from the 1st to 4th metatarsal markers, and from 2nd metatarsal head to midfoot markers. The distance between 2nd metatarsal head and ball of heel markers increased in the corrected casts ($0.05 > p > 0.02$). This is consistent with the abduction and dorsiflexion of the forefoot caused by the pronatory forces applied to the midtarsal joint, which would be expected to increase the distance between the heel and forefoot markers.

Direct measurements from the casts were compared with digitised data points. The distance from the 2nd metatarsal head to ball of heel markers in the y direction was within 2 mm for all 13 feet. This corresponds to the stated accuracy of ± 1 mm for each data point.

A selected cast was digitised twice on different days to check repeatability of the method. Although the data files from the first and second digitisations contained a different set of coordinates due to the random spacing and measurement orientation, no difference could be detected visually in either the polynomial curves or the plots of slope angles on a comparison diagram. To check for sensitivity of the results to possible digitisation errors in the markers, the raw data file for one cast was edited to move the first marker a distance of 2 mm in the X direction; no significant change in the values of the slopes resulted, although the displaced point clearly lay off the transverse curve defined by the polynomial fit.

The transverse slopes are presented graphically in figure 4.7. These results can be seen to be subject to a degree of foot-to-foot variation. On average the slope profile reaches a plateau in the heel area, at an angle of 8° (free) and 3° (corrected) forefoot inversion relative to the heel. The slope profile does not plateau in the forefoot region. In figure 4.7, differences between the free and corrected casts are presented. These demonstrate that the majority of the differences develop between slightly posterior to the forefoot plane to the midfoot. Significance t-tests show that differences are significant ($p < 0.01$) for all slices proximal to a location about midway between the 1st metatarsal head and the midfoot.

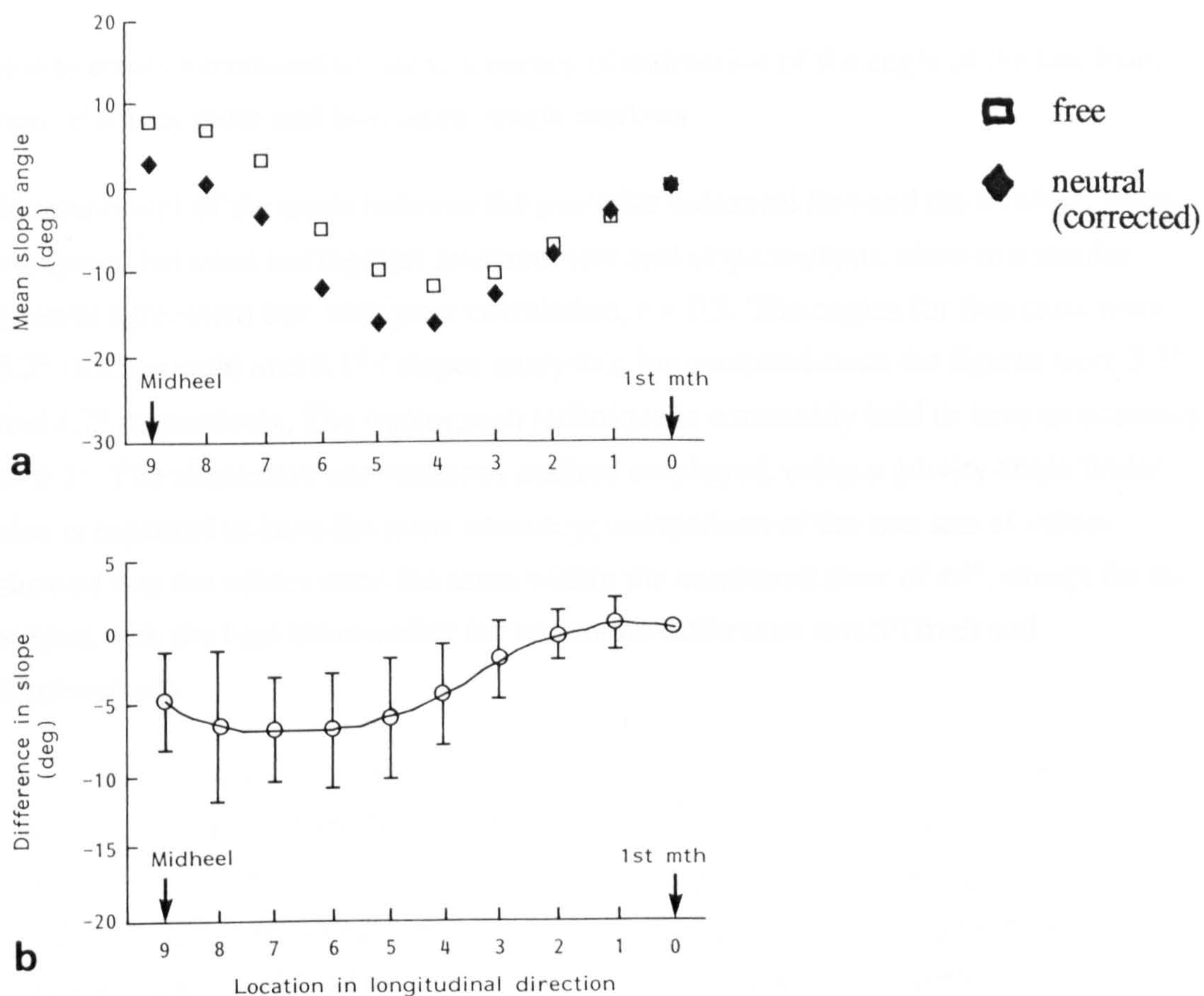


Figure 4.7 (a) Profile along the plantar surface of mean slope angle for free and neutral corrected casts. (b) Difference in slope angle between free and neutral casts. For all subjects $n=13$.

One subject gave results at the extreme of most values measured. Subsequent re-examination of the patient showed a pronounced bump in the midheel region, probably a soft tissue bursa. This abnormality caused a distortion in the slopes in the heel region. Another subject showed hardly any alteration in slopes between the free and corrected cast, an observation supported by conventional measures of forefoot rotation taken from the casts. This foot is in fact clinically rigid. Both of these subjects were asymptomatic and not previously diagnosed as abnormal, and therefore their results were included although leading to increased variability.

Some estimation of the orientations in the rear foot are also made, by consideration of the line along the posterior aspect of the calcaneum with respect to the slope of the midheel plateau. In the X-Z transverse plane (i.e. viewed from the rear of the foot) it is expected that the line will be approximately at right angles to the slope of the plateau. The angle was estimated from markers 6 and 7 at distal and proximal ends of the line and the slope at slice 9 as analysed above. The results showed angles of 1.0° (SD 4.5°) for free casts and 1.6° (SD 4.6°) for corrected casts. The large variance may be

due to errors introduced by the inaccuracy of estimation of the angle of the line from two relatively close and inaccurate single markers.

Measurement of the angle between the posterior calcaneal line and the forefoot, when compared between tractograph measurement and slope analysis, showed a similar general agreement but with poor correlation, $r = 0.5$. The angles for free casts were 8.2° (tractograph) and 9.1° (slopes analysis); for corrected casts the figures were 3.2° and 4.7° respectively. The tractograph technique is commonly held to have an accuracy of $\pm 2^\circ$. The alternative conventional method employed, using a gravity angle finder, also is expected to have the same accuracy; comparison of the two sets of values showed that the values were the same within the combined error of $\pm 4^\circ$, except for the subject with the heel abnormality for whom the difference was 8° (free) and 6° (corrected).

4.4 DISCUSSION

A method has been presented to estimate the transverse slope of the plantar surface of the normal foot along its length. This method uses digital shape definition and analysis to provide a repeatable and robust result, so that a meaningful comparison of the slopes in the free and forefoot-corrected orientations can be made. The limited accuracy of the digitiser employed has been ameliorated by taking great care with the data capture procedure, and by curve fitting through slices of fairly dense raw data. Accuracy tests on a cylindrical object of similar geometry suggest that the curve will be accurate to the surface to within 0.5 mm over the central areas. Individual points captured as markers are subject to larger errors, but these are only used for initial orientation and delimitation of gross areas of interest.

In routine clinical assessments of the transverse slope of forefoot with respect to heel, the slope is usually determined by a line across the two high points which usually occur in the vicinity of the 1st and 4th/5th metatarsal heads. In the digital analysis a similar technique was attempted but proved sensitive to small changes in the data. The method finally employed, fitting a regression line through the polynomial curve, gave equal weighting to every point on the curve. This was insensitive to introduced errors in individual data points of the order of ± 1 mm, and also to the exact boundaries of the delimited area. However the slope determined in the midheel region for a subject with a pronounced surface bump was not a reasonable estimate of heel plane, and further refinement will be required to cater for abnormalities of shape.

An area of the plantar surface was delimited for consideration of the transverse slopes. This region was not extended out to the 5th metatarsal head. The fifth metatarsal can move in a sagittal plane independently from the metatarsal medial to it, and probably does so when depressed manually during correction; also the thumbprint in this area of the cast is filled to an arbitrary depth. Inclusion of this area produced a greater variability of results, and the regression line through the reference plane at the 1st metatarsal head did not appear to be that which would be intuitively drawn as representative, being depressed by the lower curve at the lateral side. Thus the delimited region was restricted to medial from the 4th metatarsal head. A similar argument was considered for exclusion of the region under the 1st metatarsal head, since again the 1st metatarsal has mobility independent of the central three. Under free hanging conditions, it is contended that the 1st metatarsal may fall into plantar-flexion. The medial side was not excluded since the slope regression lines appeared to be reasonable representations of transverse slope.

The analysis shows that the twist, i.e. the difference between the transverse slope in the free and corrected state, is statistically significant although subject to a great deal of individual variability. Some of the variability has been accounted for due to an abnormality in the heel of one subject, and also it was noted that another subject showing almost no twist had, in fact, a clinically rigid foot. The variability may therefore be partly due to real clinical features, although also partly due to sensitivity of the analysis technique.

On average, the twist induced by forefoot correction is largely occurring over a very limited length from the vicinity of the midfoot marker to proximal to the metatarsal heads. Anatomically, the midfoot marker is just anterior to the midfoot articulation of the talus/navicular on the medial side and the calcaneum/cuboid on the lateral side. The results are thus entirely consistent with the majority of the eversion occurring in the midfoot joints.

Further work on larger groups of patients with a more rigorous clinical examination may enable characteristic of sub-groups to be identified, eg. behaviour of hypermobile (ie. with above normal flexibility at the joints) vs. rigid feet. The technique also needs to be refined to cope with minor surface abnormalities which at present caused unreasonable variations in the apparent slopes. This might be approached by prior assumptions about the expected contour shape, for example by best-fit of an assumed 'normal' shape.

This analysis technique has applications beyond its pure biomechanical interest. It provides a method to investigate intra- and inter-operator variability in casting techniques, whereby the degree of correction applied each time can be quantified. The influence of other casting techniques, such as foam block casting, may be investigated. Beyond this, it is also an early step towards provision of a scientific basis for computer-aided design of shoe inserts. Information gained from the investigations so far would assist the surface modifications specified for forefoot correction to be applied at the appropriate axial location along the foot. This process would attempt to reproduce in a systematic way the corrections induced manually in the second of our two casting techniques, working from a free, neutral shape scan of the foot.

4.5 CONCLUSION

This chapter describes an attempt to quantify one aspect of the correction of plantar shape which a CAD system might attempt to simulate, namely the axial twist which is built into a posted semi-rigid insert. It is demonstrated that, on average, the twist is developed in a fairly prescribed area of the midfoot when the foot is everted by hand. It can be concluded that a good computer simulation should impose the twist over this same area on an unrectified foot cast, in order to simulate the corrected shape which would be induced by manipulation.

A method to obtain a gradient with which to quantify the axial twist has been developed, and its reliability explored. Although appearing a reasonable algorithm for extracting the characteristics of the group, individual results may be distorted. One subject showed inconsistent results because of a bony spur, but the technique successfully highlighted a rigid foot. This would indicate that although hopeful, further work is required if individual shapes are to be analysed in this way eg. as a measure of plantar inversion.

Acknowledgements

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CHAPTER 5. SHOE UPPER DESIGN

5.1 BACKGROUND

In previous chapters, factors relating to the design of the shoe insert has been explored. In this chapter, the design of the upper part of the shoe is considered. Design of shoe-uppers is a complex process which needs to meet requirements of both function and aesthetics. The majority of orthopaedic manufacturers meet this need through very skilled craftsmen, who create paper patterns mostly by presenting the paper up to the last and drawing out the required pattern pieces by freehand.

However, advanced technology is already widely used in the volume shoe trade for design of patterns for shoe upper, and it is an obvious step to investigate the applicability of the available techniques from this sector to the smaller industry of orthopaedic footwear. In the volume trade, the designer draws new styles on the computer screen. From these images, patterns can be generated automatically for each size in the required range (known as 'grading') and then output directly to a cutter to produce appropriate leather pieces. Many of the current systems work in 2-D: the patterns are drawn on a flat sheet which represents a flattened form of the shoe last upper. However the latest generation of system provides some 3-D capability in varying degrees. A 3-D upper design system, 'Shoemaster' * has been used in the experimental work of this chapter, and is described fully below. In this system, a 3-D representation of the shoe last is shown on the screen, and design can take place by drawing over this 3-D surface.

Although pattern generation is an essential stage of orthopaedic shoe making just as for the volume trade, the applicability of volume systems to the very different problems of bespoke shoe design does not automatically follow. Primary advantages for the volume trade are speed of development of new style ranges, ability to grade automatically to different widths and lengths for a size range, and integration into the production process eg. in specification of stitching patterns, efficient material layout, planning and costing. These are less relevant if at all to one-off bespoke manufacture.

The value of using this type of pattern-design CAD system can be foreseen in other areas. Improved cosmesis might be gained through the availability of a range of styles on the system library, and the accuracy/consistency of pattern generation for each style could be secured through automated processes. Additionally, the speed of pattern

* Shoemaster, Clarks Shoes, 40 High Street, Street, Somerset, England BA16 0YA

generation might be increased, although this in itself would make only a marginal difference to the overall production delay (hand method approx. 15-30 minutes, machine generation perhaps less than 5 minutes, against a total production time up to 6 weeks). Indeed in isolation, the upper design system might have limited commercial value, but benefits of CAD begin to accrue when more of the production process is linked together. An ultimate goal for the application of advanced technology must be to automate the entire design process, from live shape scanning of the foot through to production of the last, the shoe upper and any shoe insert required. The consideration of any component part of the system should therefore take into account the potential for integration into a full CAD system for shoe design. This topic is taken up in the following chapter.

It is not necessarily true that a good pattern design system for the volume trade will function satisfactorily for orthopaedic work. In the latter, a range of abnormal last shapes are encountered for patients with foot problems, and a question must be raised as to whether the CAD system is versatile enough to encompass this range. In particular, the flattening process from surface of the 3-D last to the 2-D pattern is critical, and this will be far less standardised than for commercial fashion last shapes.

The trial described in this chapter was initiated to investigate the applicability of an existing 3-D pattern design system for orthopaedic work. The chosen system, Shoemaster from C & J Clarks International, is currently used internally by Clarks Shoes for pattern design in both 2-D and 3-D, and sold commercially to other shoe manufacturers around the world. Its implementation allows for a full 3-D surface representation of the shoe last, which obviously opens up possibilities also for last design. Indeed the developers have conducted preliminary work towards this end already for the volume trade. This clinical trial was not intended to be a demonstration of how the design system might work in orthopaedic service. Rather, the more limited and directed aims of the trial were to

- confirm that an existing CAD system for shoe uppers is technically able to cope with orthopaedic shoe requirements,
- assess the impact of professional design to produce fashionable and cosmetically-pleasing styles within the constraints imposed by the underlying medical conditions, and
- explore the potential to integrate into a complete computer system for design of both shoe lasts and shoe uppers.

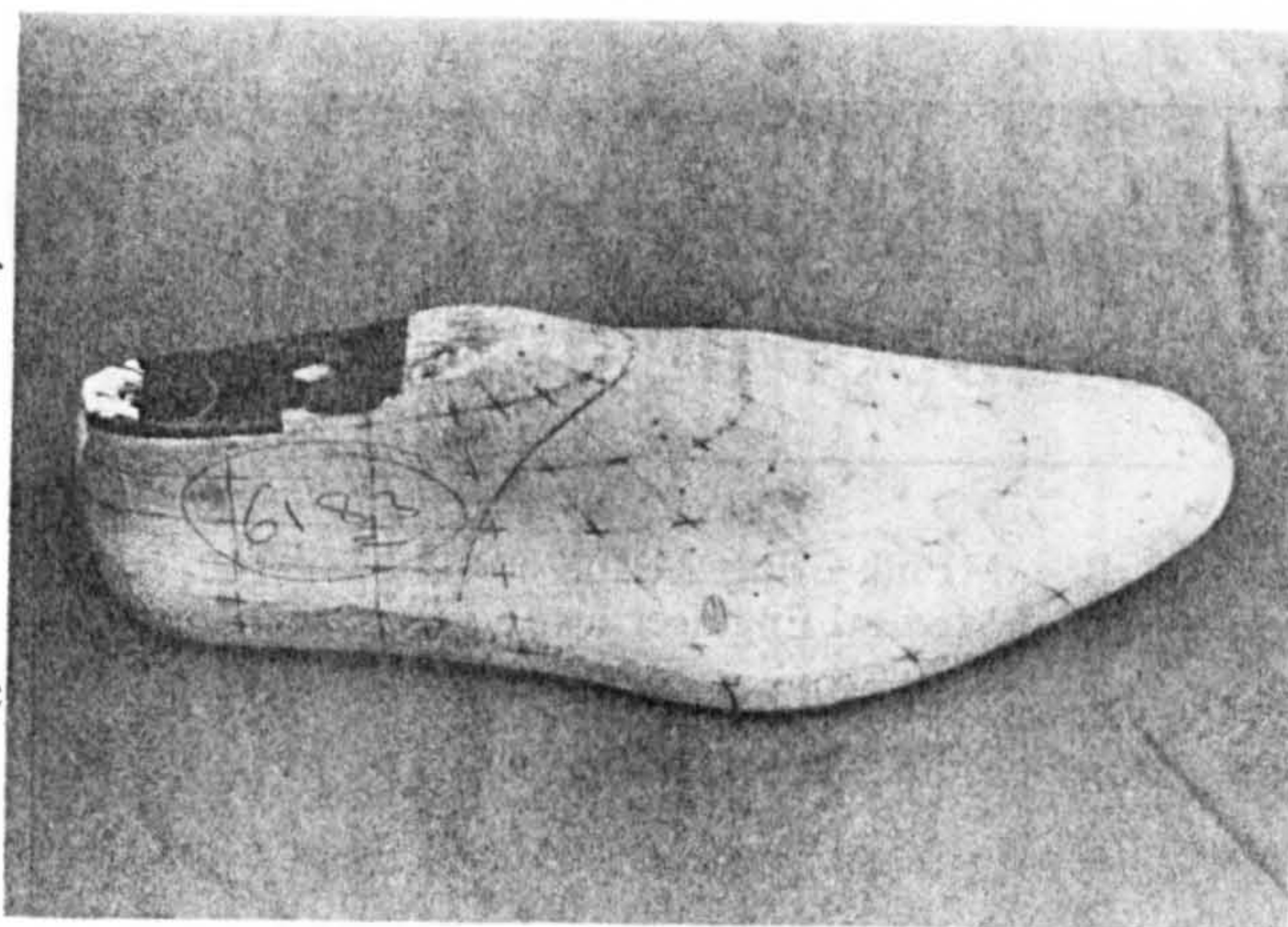
The clinical aspects of the work described in this chapter have been published by Lord & Foulston (1991) and the technical aspects in Lord, Foulston & Smith(1991). The trials were a team effort with Lord the director to generate funding and protocols, document and analyse results: Foulston as the clinical coordinator and patient interface: and Smith providing the technical input for the CAD design system.

5.2 DESCRIPTION OF THE UPPER DESIGN SYSTEM

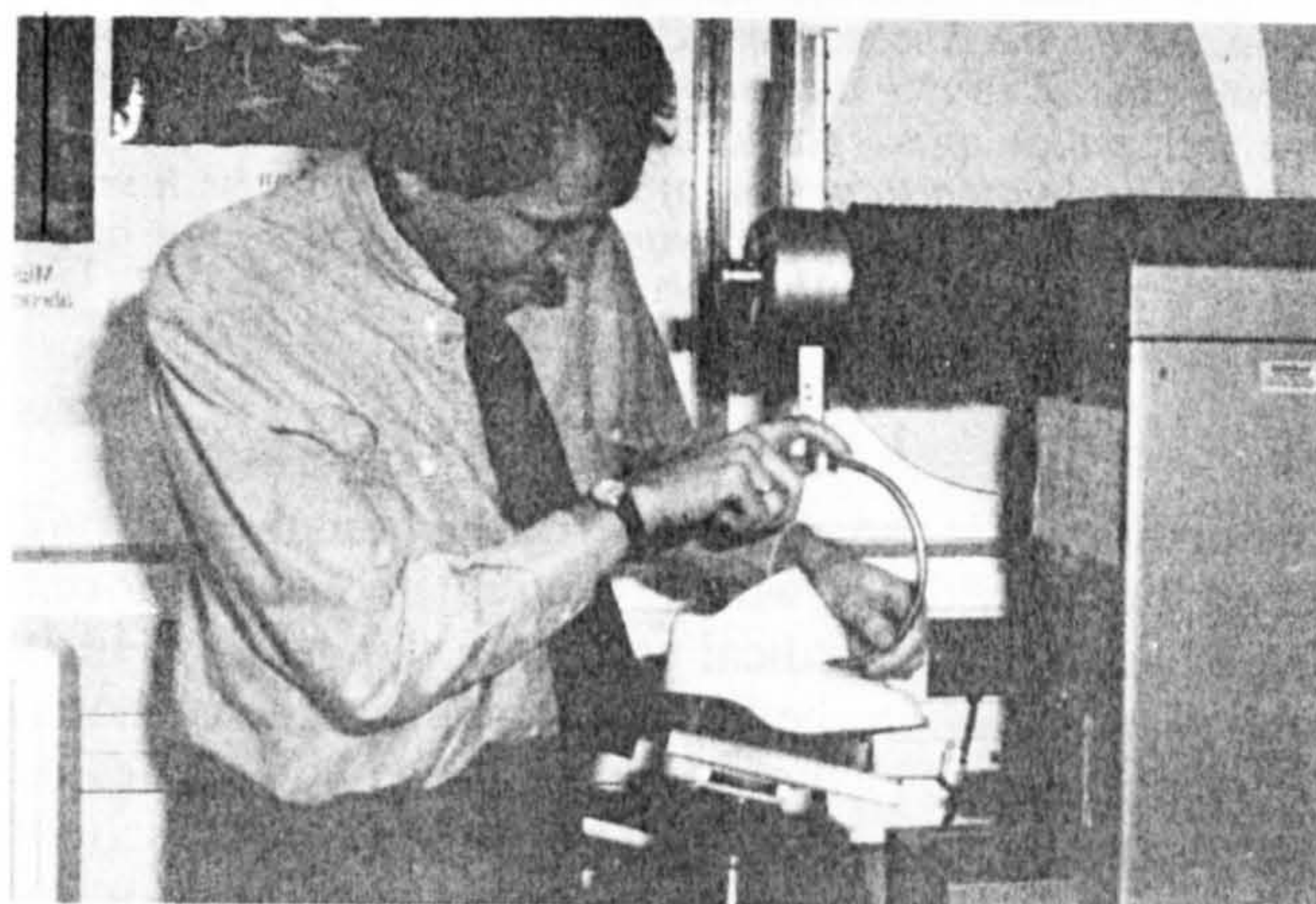
The trial has been conducted on a 3-D design system, Shoemaster^{*}. At the heart of this system is a model of the shoe last. The last shape is initially input into the computer by a method of hand digitisation. The last is marked up with a structured grid, figure 5.1a; one of the lines runs along the feather-edge which delimits the upper from the sole. The intersection points of the grid are then fed into the computer, figure 5.1b. From this set of surface coordinates, two parametric surface functions are generated for the upper and sole respectively. The limited set of coefficients for this parametric function completely define the surface at all points.

At the start of a design session, the model of the last is displayed as a shaded surface on the computer workstation, figure 5.2a (Unix-based Hewlett Packard). A wireframe representation can also be displayed. A sole unit can be

added from a library, mapping itself to the bottom edge of the chosen last. To develop the shoe style, style lines are drawn on the 3D image. A wide selection of line styles are available to indicate stitching, cutting and punching. In figure 5.2b the inclusion of decorative stitching is shown. When sufficient style lines have been drawn to define the shoe outline and pattern, colour can be specified. The last is then 'removed' to give a realistic view of the finished shoe, figure 5.2c.



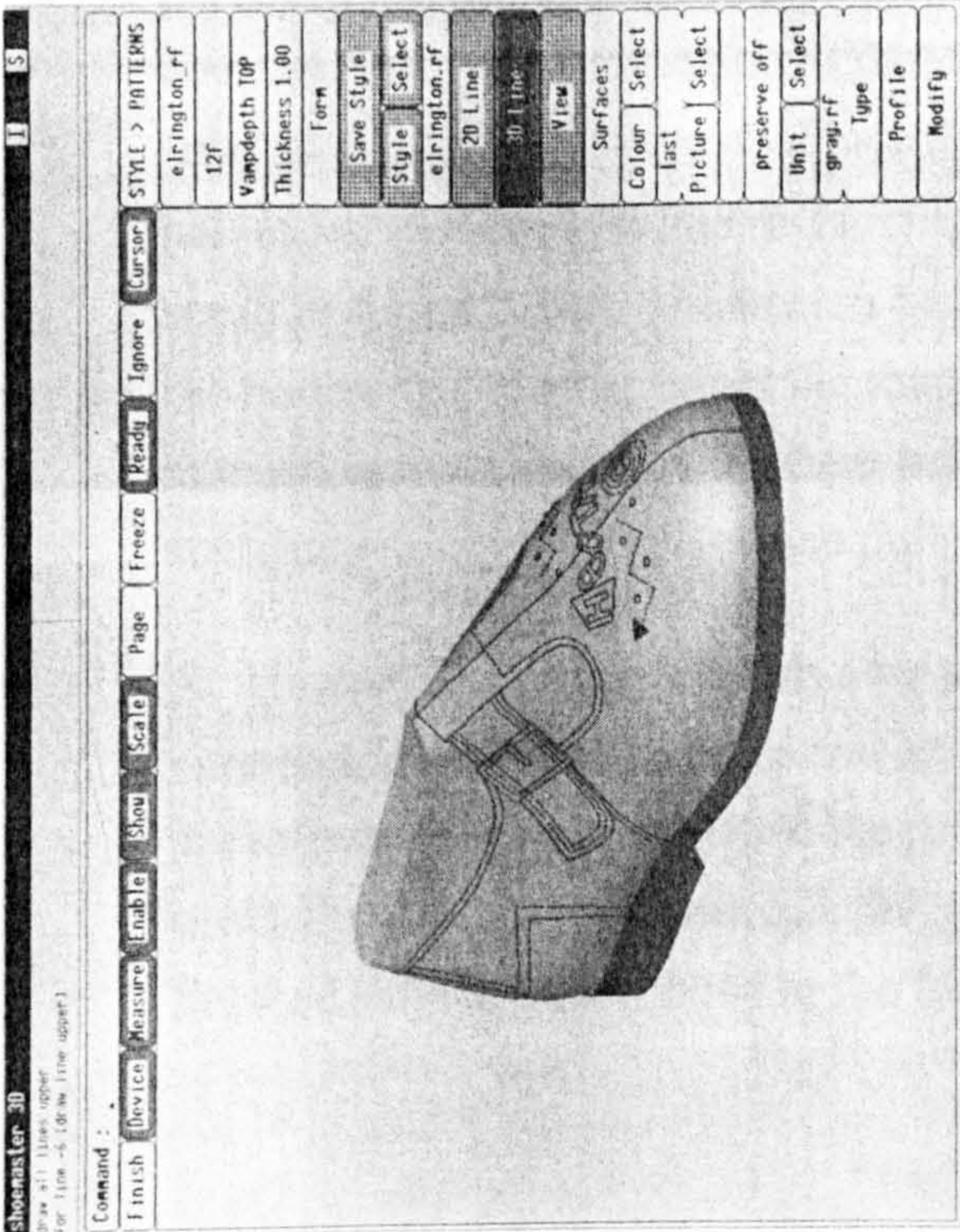
(a)



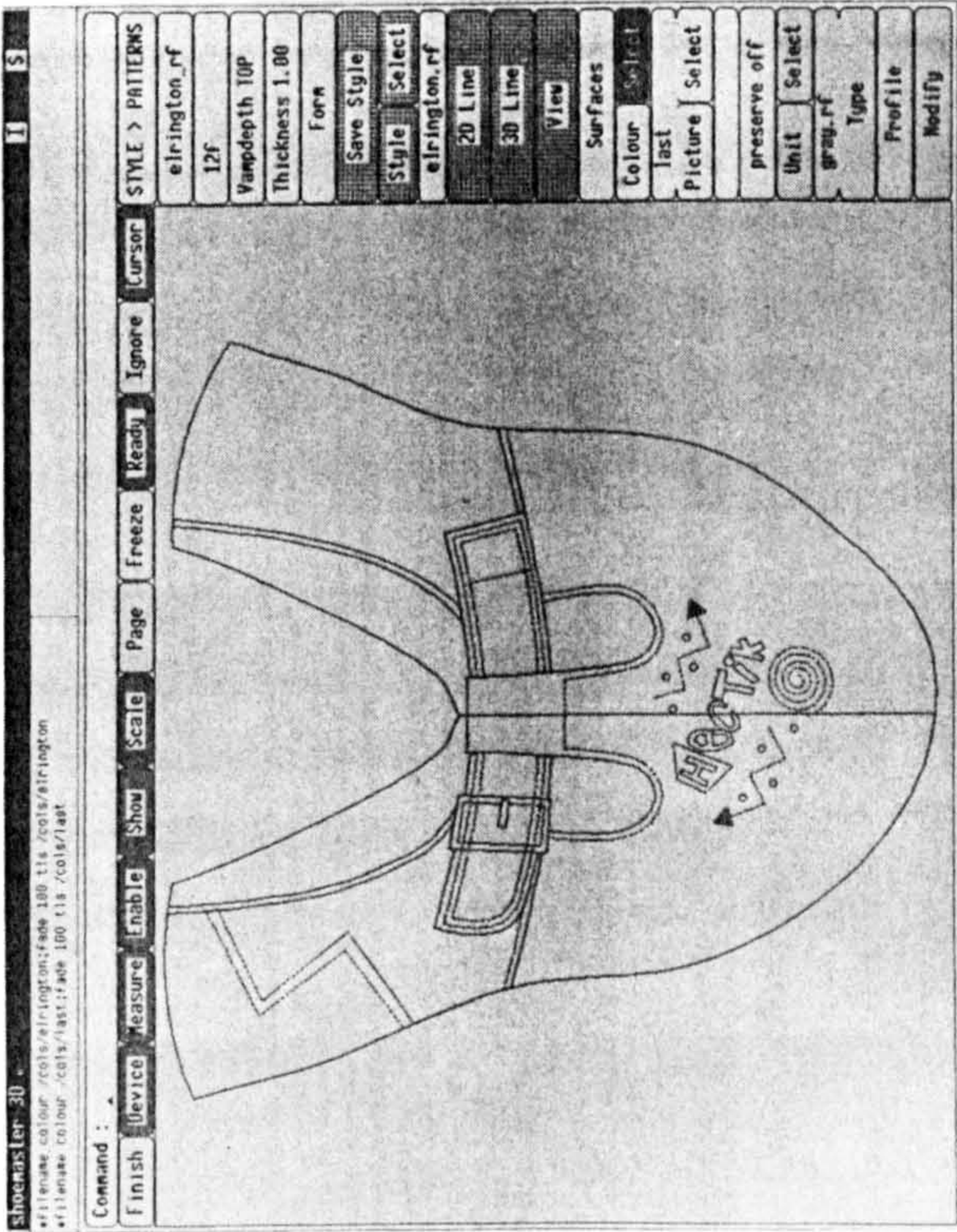
(b)

Figure 5.1 In the digitisation process the shoe last is (a) marked up with a grid and then (b) digitised manually.

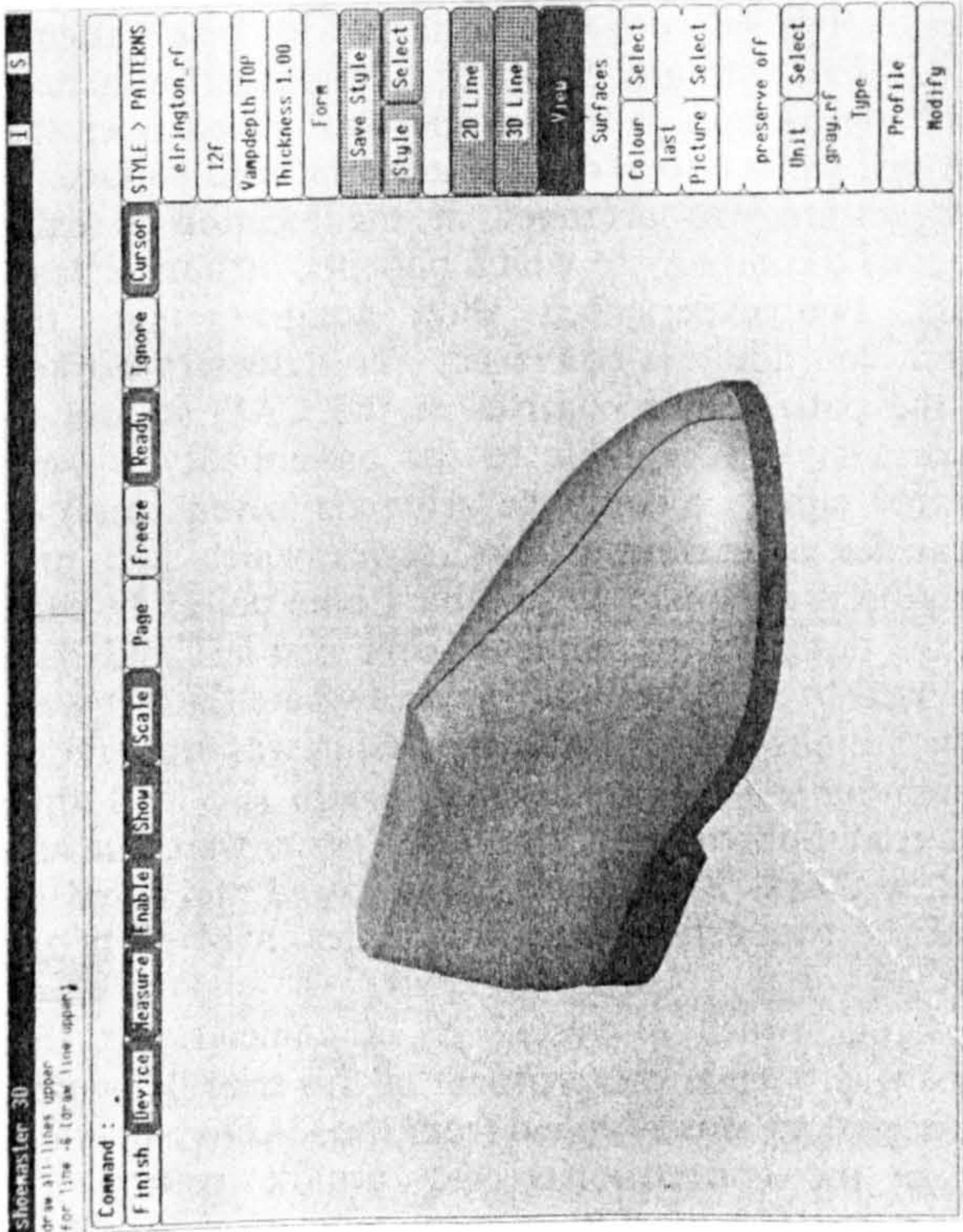
^{*} Shoemaster, Clarks Shoes, 40 High Street, Street, Somerset, BA16 0YA



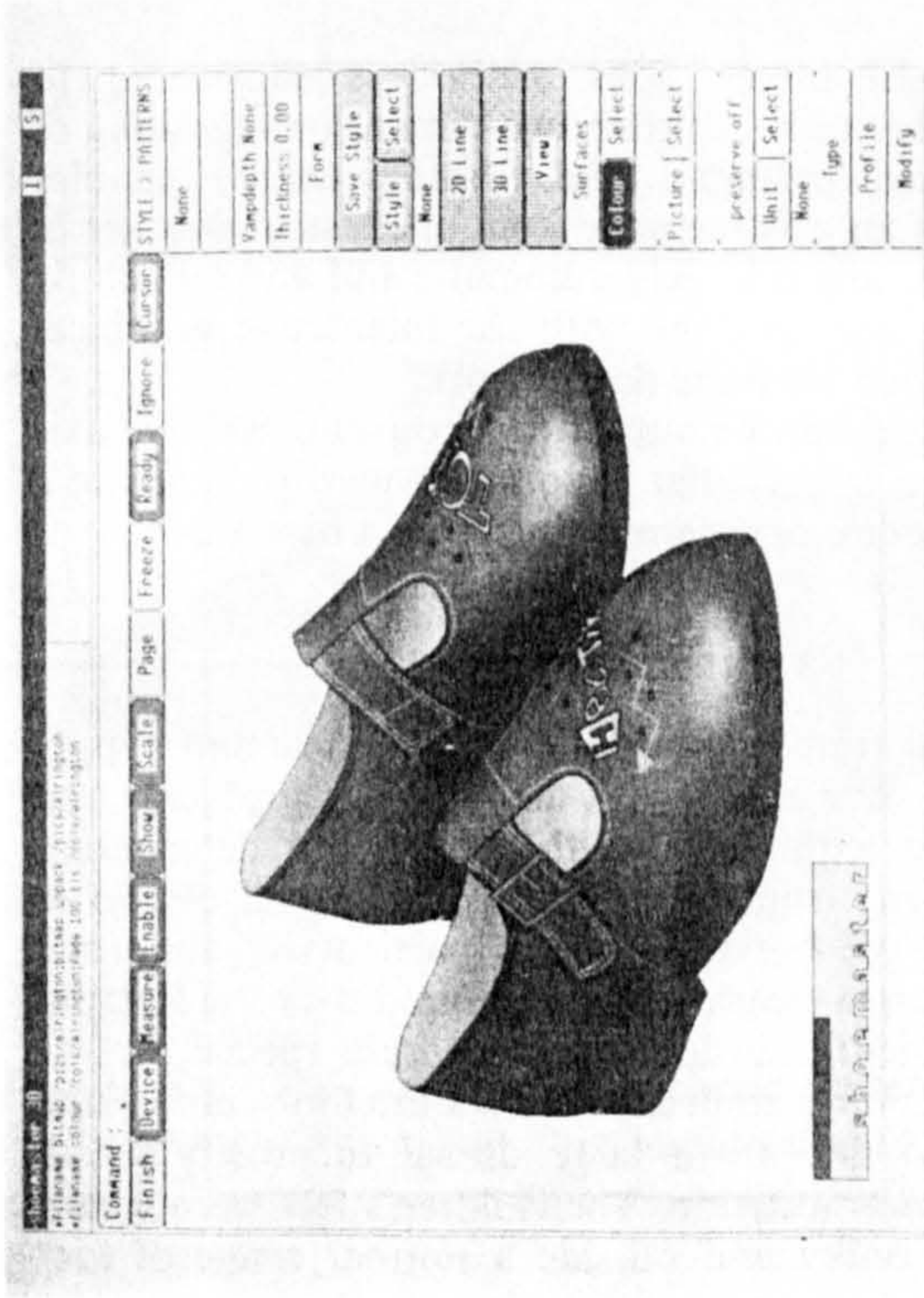
(a)



(b)



(c)



(d)

Fig52 The process of on-screen design starts (a) with the shoe last and an added sole unit, (b) the style lines are added and finally (c) the last is 'removed' and colour is added for a realistic impression of the shoe. (d) The flattened representation is always available

At any point in the design process, the corresponding flattened pattern pieces can be displayed. It is sometimes easier to add certain features onto the 2-D view, such as circular patterns or straight lines, and then to convert back to 3D. Flattening is the result of a complex algorithm which takes account of the way in which the flat leather pieces will eventually need to stretch around the last during shoe fabrication. This consists firstly of an operation to flatten the two sides split down the centre line (medial and lateral) separately. Since this operation causes the centre line to distort, the halves are then brought into registration by rotation and fused together to achieve the result in figure 5.2(d). The degree of and point of rotation determines the 'spring' of the flattening (to what extent the shape will spring into a curve when sewn together), and makes a compromise of where material will be lost and gained - resulting in stretching or extra material when pulled over the last.

At this stage the designer hands over to the pattern engineer, who works with the 2-D view to add lasting allowances and optimise pattern layout with the special facilities of the software package, and then the pattern is output to a choice of numerically-controlled cutters. In figure 5.3, the pattern pieces have been cut and closed, and the finished shoe is shown fitted to the foot.

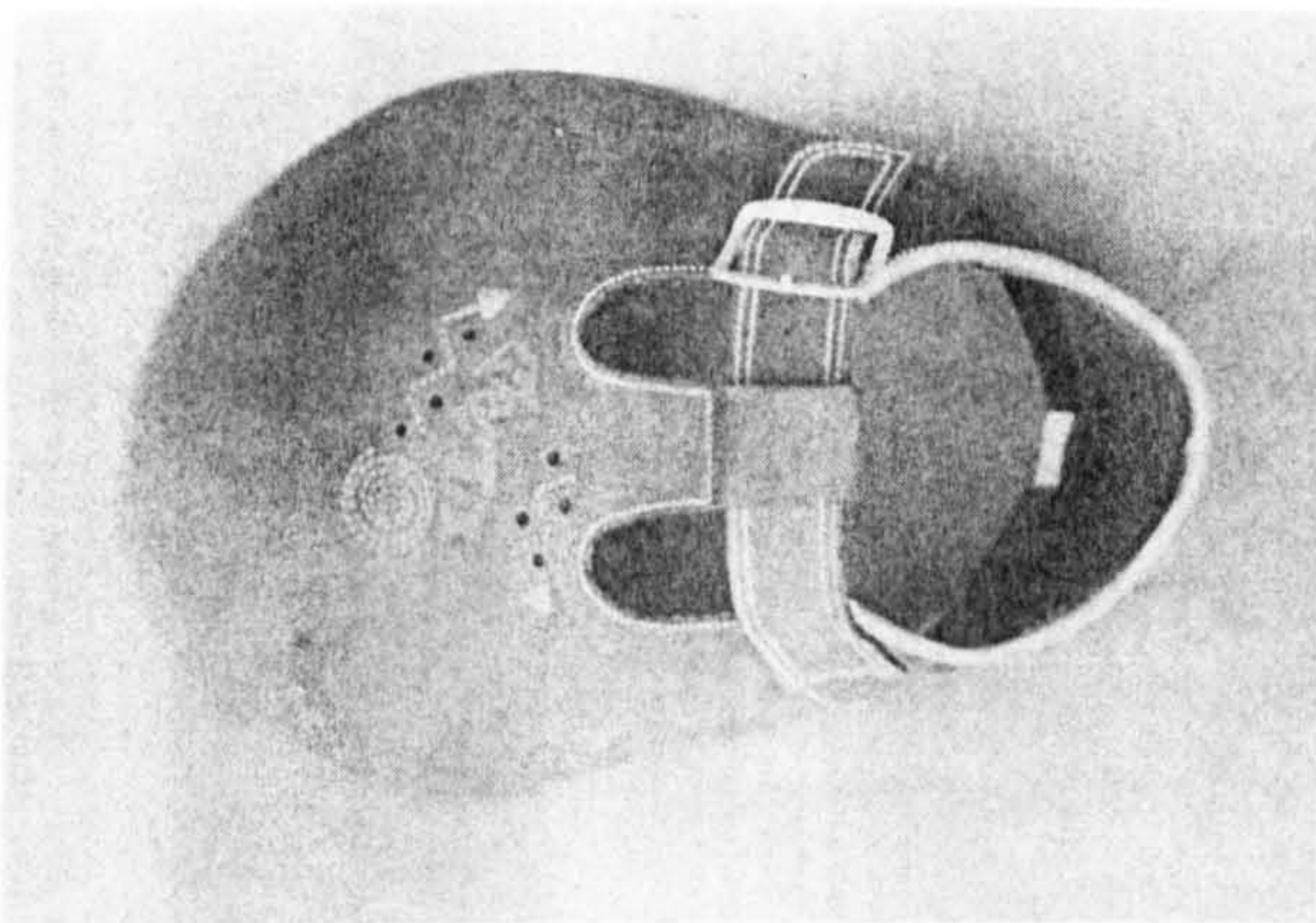


Figure 5.3. The closed upper is shown corresponding to the design in figure 5.1. The completed shoe is fitted to the patient.

Figure 5.4. This adult male diabetic patient had undergone forefoot amputation due to vascular insufficiency. His shoes minimised his deformity

The system has two important software features in addition to the basic design application, namely grading and transfer. Grading enables the generation of different sizes of last from a single stored last model; in Shoemaster grading is done on the 3-D model and each model is flattened to generate the correctly-sized pattern pieces. This method is considered to produce a better result than 2-D grading of the flattened patterns. The transfer facility enables mapping of an existing style from one last to another of similar size; this is largely automatic and any remaining fine tuning can be done with the interactive graphical tools provided for basic design work.

The system as used at present transfers styles in 2-D space: the library style is represented on the flattened form of its reference last, and the lines are mapped over one-for-one onto the flattened form of the target last. Once in place on the target flattening, they can then be reflected immediately onto the 3-D model. This is referred to as 'real-space' transfer. An alternative method is possible in a limited sense at present, referred to as parametric transfer. In this system, the lines are mapped in parametric space directly from one 3-D last to another. The last upper is described mathematically by a surface which has parameters u & v ; u describes the position across the last in the mediolateral direction, whereas v describes the position along the last in the anteroposterior direction, and each parameter runs from 0 to 1 irrespective of the last dimensions. The style lines are transferred so that they pass through the same u, v points on the reference and target last: hence all the styling lines originating at points along the featheredge of the reference last will be guaranteed to transfer to the featheredge of the target last, and so forth. The current restriction on parametric transfer is caused by the initial parametrisation of the surface, which is not arranged to identify key landmarks which should be mapped exactly. Such key landmarks might include for example the vamp point (at the base of the lace panel for an ordinary Gibson style), the underankle top-line and the top of the backseam. Further extensive work is required to define appropriate key landmarks, and to ensure that these lie at standardised parametric coordinates of the surface model.

Last shapes can be output to a conventional 5-axis CNC mill, a facility which is normally used to generate a range of models of different sizes from a new model.

5.3 METHODS

Trial Design

It was decided to restrict the clinical trial to three groups of patients with similar foot problems of typical features of their lasts & shoes. Following discussions with clinical colleagues, these were identified as the diabetic foot (extra-depth insoles, high toe box), spina-bifida foot (bulky instep area and severe deformities in shape, including size differences between left and right) and rheumatoid foot (wide shoes in the forefoot, soft uppers, easy access). Established patients who had recently been supplied with shoes should be chosen, so that a last known to be satisfactory would be available; the trial would thus be only of the ability of the CAD system to design patterns to that last.

The trial clearly needed to involve both the Shoemaster team to provide the CAD facilities, clinical facilities to identify and see the patients, and at least one orthopaedic company to make the lasts available and fit the shoes. Agreements for covering costs needed to be considered. Clarks Shoes agreed to cover their own staff time costs in designing the shoes and also the costs of providing a pair of closed uppers for each patient. The following arrangements were made:

Diabetic patient group: 6 adult patients to be identified by Mr S Lloyd , orthotist from L S B Orthopaedics in Birmingham, with permission sought by KCSMD staff from the patient's consultant: to be seen at LSB headquarters in King's Norton, Birmingham. Costs: LSB agreed to cover their own costs of staff time, shoe manufacture and fitting. The British Diabetic Association sponsored the expenses of the KCSMD team (travelling costs and time for J Foulston) and the travelling costs for the Clarks team.

Spina-bifida group: 6 children to be identified by Mr C Peacock of J C Peacock and Son Ltd in Newcastle, who would also obtain consultant's permission: to be seen at a local hospital in Newcastle. Costs: J C Peacock agreed to cover their own costs of staff time, shoe manufacture and fitting: Clarks Shoes sponsored the other expenses of their own team and KCSMD.

Rheumatoid group: Not continued due to failure of funding negotiations with a charitable trust.

Procedure

Two research shoe designers from Shoemaster first visited the diabetic foot clinic at King's College Hospital and discussed with clinicians and patients their requirements for orthopaedic shoes. Constraints on style were that the final shoes should be suitable for the medical condition. This mostly meant outdoor walking shoes with adequate instep fastening. The senior orthotist from each of the collaborating orthopaedic shoe companies selected subjects for the trial according to a protocol developed by the author giving the following constraints:-

- a. Subjects should recently have been issued successfully with special shoes for which recent lasts were available. For children, if there had been growth since the last pair of shoes, the feet should be remeasured and the existing lasts modified accordingly.
- b. Patients selected for the trial should have the ability to help in the design of the new shoes and be well enough to attend the clinic for consultation and fittings.
- c. Any internal orthoses or modifications to the shoes to accommodate external orthoses can be included.
- d. LSB Orthopaedics Ltd were asked to identify adult patients with diabetic foot problems (insensitive feet needing cushioning), and J C Peacock & Sons were asked to identify children with foot problems typical of spina bifida (bulky midfoot, different sized feet).

The patients' lasts were sent for digitisation at Clarks where the surface of each last was captured with a stylus digitiser. Any cradle or insert allowance was added to the last before digitisation. Lasts which had previously been modified with soft additions or which had fairly rough exteriors, thus making their surfaces unsuitable for the stylus, were vacuum draped with thin thermoplastic before application of the digitising probe.

The shoe designers brought the CAD system to the patients at the two clinics, where the designer and patient together sketched the shoe style on-screen over the three-dimensional view of one of their own lasts. The orthotist and orthopaedic last-maker were on hand for consultation. The preliminary designs produced on the computer in the clinic were later completed for that shoe. The final design was then mapped over the last shape for the other foot and the two shoes harmonised as a pair. For example, where there was one short foot, the shoe styling lines were managed in such a way as to make a proportioned *pair* of shoes.

After the design is completed, the 2D pattern pieces corresponding to the 3D image were engineered on-screen to include the correct cutting allowances etc. Leather was cut by computer controlled machinery and subsequent closing performed in the factory. This included the use of automated decorative punching and stitching to achieve the special effects called for in the design. The closed uppers together with the original lasts were dispatched to the orthopaedic shoe makers where the shoes were lasted and finished. The children's shoes were trial fitted before final finishing because of the possibility of growth. Shoes were issued to the patients with care being taken to assess fit and solicit reactions to cosmesis. Follow-up assessments were made to check that the patient had been caused no problem by the footwear, for fit after wear, to seek the subjects' subjective views on style and fit and to observe the state of the shoes after they had been worn .

A repeat order requested by a clinician for one patient was outwith the protocol of this trial. However, a paper pattern was supplied from the CAD system, and used in the conventional way at the orthopaedic company to manufacture a new pair of shoes. Both leather and lining patterns were supplied.

All procedures were closely observed by the company orthotist, the last-maker, the design engineer and the research team. Technical aspects of the procedure, including any difficulties encountered, were noted alongside the clinical aspects.

5.4 RESULTS

Patients

The list of subjects, their background medical condition, the condition of their feet, and the CAD shoes made for them is shown in Table 5.1. Only four of the adult patients arrived on the day of the trial : one proposed patient was deceased and another declined to attend. The six children all attended and typically had very deformed feet with bulky midfoot areas, mostly resulting from spina bifida. In two cases orthoses extending above the ankle were worn: one patient wearing moulded ankle-foot orthoses and the other exterior short leg braces. The four adult subjects were all diabetic; two pairs of feet were intact and of fairly normal shape but prone to lesions, one man had undergone a forefoot amputation (figure 5.4), and another lady had very sensitive and swollen feet following a recent operation since which she had not worn shoes at all.

Fit and Cosmesis

All of the six children were successfully fitted. Both children and parents were very pleased with the 'high-street' appearance of the shoes. Three of the four adults were happy with the shoes provided. The fit was poor for the fourth adult, mostly due to lack of communication about the depth of special insole to be provided. This prevented the shoes being issued, but the patient was pleased with the style and at her request another attempt will be made to obtain a fit when a small lesion noted at the fitting visit has healed.

There were no major obstacles in the design or lasting processes although several points which require attention emerged during consultation between the coordinators, the orthopaedic companies and the staff at Shoemaster. Detailed observations at the various stages of the process are given below.

Subject	Sex	Age	Medical condition	Description of feet	Type of CAD shoes made
1.	Female	75yrs	Diabetes NIDDM (7yrs)	L large dorsal tuberosity at 1st MP joint.	Yellow Derby style lace up.
2.	Female	69yrs	Diabetes IDDM (33yrs)	Neuropathy, unsteady gait.	Red lace ups. D buckle & U shaped closure.
3.	Female	64yrs	Diabetes/oedema	Surgery for equinus feet Hypersensitive feet.	Lace up. Reddish/brown
4.	Male	52yrs	Diabetes/ischaemia IDDM (10yrs)	Amputation R toes 1-5 Amputation L 1st toe.	Black lace-ups.
5.	Female	14yrs	Congenital left club foot short left leg & foot.	Equinus left foot, history of surgery.	Brown brogues with subject's punch design.
6.	Male	14yrs	Congenital club feet.	History of surgery. Pronated feet.	Trainer type. Blue & yellow.
7.	Female	10yrs	Congenital spina bifida Neuropathy & muscle wasting.	Needs to accommodate thermoplastic AFOs. Pronated feet.	Clarks "Hectik" purple suede shoes - T bar & buckle.
8.	Male	9yrs	Congenital left club foot.	History of surgery, short left foot with varus forefoot	Grey Clarks "Hardware" with yellow lace.
9.	Female	6yrs	Congenital equinus feet.	Recent surgery, pronated & abducted feet.	Patent purple shoes with flower applique.
10.	Male	3yrs	Congenital lymphodema (Milroy's disease).	Feet very oedematous but with normal bone structure.	Black & white trainer type

Table 5.1 Details of the patients on the trial.

The Design Process

Patients' preferences: Patients generally came with a clear idea of what they would like in broad terms of style and functional requirements. Two of the boys wanted their new shoes to look like trainers and one of them had come with a previously prepared coloured diagram . The other children were encouraged to select from current Clarks styles which were displayed on example shoes, which three did. The designers brought a selection of patterned laces, fasteners, buckles etc, all of which could be used on the final shoes. They also suggested other features, such as a soft top edge used for the pair of laced walking shoes requested by one lady.This proved to be a

particularly beneficial exercise as the subjects had not previously considered the possibilities for these important styling additions.

The time taken with the designer and patient together for sketching one of the proposed shoes onto the computerised last shape was in the order of an hour to an hour and a half. For current Clarks styles, the pattern was called up from the library and mapped over the individual's last, which took far less time to achieve. The designers needed subsequent additional time to tidy the design, to map it over the other last and except for the existing styles, to do the essential pattern engineering (add lasting allowances etc.).

Symmetry: With original designs, the normal practice of reflecting the design about a straight line down the middle of the last could not always be practised. This is due to the unusual shapes of the lasts. Nevertheless the CAD system allows the option to develop each side separately, and this was therefore not a problem.

The designers spent considerable time to achieve the correct cosmetic 'balancing'. This process is not needed with the normal symmetrical pair, and the CAD package does not have the facility to display the right and left last at the same time during design for comparison. This made the process longer than would otherwise be necessary. By maintaining each shoe roughly in proportion with features on the apron (front quarter) as near as possible the same size, a very good result was achieved. The transfer of patterns did not result in any distortions of, for example, decorative stitching and their placement, and the proportions of the various parts of the shoes were maintained reasonably in balance.

Design problems from high mid-foot:- Two of the children's shoes with a T-bar tended to gape on the upright of the 'T', which can be seen by close inspection of the right shoe in figure 5.3. Problems were also experienced in this area with lace-up shoes, where the panel was held too wide open. In all cases, this occurred where there was considerable foot deformity in the midfoot with increased girth and height. It was noted from screen copies that the problem did not appear on the 3D image, indicating that the problem occurred in the flattening stage. The flattening algorithm is sensitive in this area, and future software development is indicated, although this was not a severe problem. Indeed the research team noted the gaping, but no patient commented on this.

Sole-units:- During design, an arbitrary sole-unit was selected from a library of such units available at Clarks Shoes. It was noted in passing that the sole unit fits exactly around the base of the custom last, rather than appearing as a standard size and width,

so that the individual last shapes presented no problems. The shoes were eventually lasted and the soles provided at the orthopaedic company, where special features such as heel flare were occasionally required. Print-outs of the screen design were not made available at the time of lasting, and the difference between the sole-unit on the screen print-out and that supplied in practice could influence the cosmetic appearance considerably.

Back seam and under-ankle heights:- The designer draws onto a representation of the last, which in the orthopaedic case included any special inserts and allowances. This leads to confusion as to what is space for the foot and what is space for the insert. If the designers draws a top line in what appears to be the normal position, then this may result in a shallow shoe around the heel and under the ankles when the insert is in place. In practice the seam allowances were sufficient to allow for correction at the time of lasting, but resulted in tight working.

Paper patterns:- Paper patterns were found to be useful for the production of a second pair of shoes for an adult patient. The computer system generated both upper and liner pieces, with the liners slightly smaller. It was not the normal practice in the orthopaedic company to use different patterns due to time involved in their production, but the orthotist considers that this gives a superior result and should be used if the CAD system can automatically generate liner patterns with no time overhead.

Lasting the Shoes

The orthopaedic companies undertook lasting the closed uppers and finishing the shoes which had been produced from large ranges of leathers available to Clarks. The special requirements and the working with some of these unusual leathers such as patent or soft leather did not present great problems although some of the standard orthopaedic procedures such as soaking puffs and stiffeners and coating the lasts with talc were found not to be suitable. Adults' shoes made from fairly 'solid' leather were machine lasted and the soft leather adults' shoes and the children's shoes were hand lasted.

The lasting allowances were found to be even but could have been slightly greater to allow for the orthopaedic manufacturing processes. The uppers fitted snugly to the lasts indicating that the patterns were accurate. The linings were slightly short and had to be "pulled" to make sure they reached around the bottom of the last.

The design of the soles on the computer was an 'artists impression' but in reality, the orthopaedic shoemaker used his discretion and skill in finishing the shoes to give a

balanced appearance and correct heel heights etc. This proved in general to be a successful technique.

Fitting and Review of the Shoes

No special problems related to the CAD system were noted with fit or wear. Very positive comments on cosmesis related to the normality of the appearance, whether for an original design or for the three cases where a Clarks style was adopted. The balancing of odd-sized shoes for some of the children was particularly successful, it being hard to determine on first inspection the larger foot.

In several cases the shoes on review were found to be wearing rather better than those normally supplied, and in one notable case, the shoes had withstood a period of three times normal without requiring the usual frequent toe-capping. This did not correlate with a heavier weight of leather being used.

On the whole, the CAD designs had more stitching than would normally be used. Some of the stitching was decorative. Care was taken to avoid stitching in locations which could be problematic, and this had not given rise to any problems of abrasion. Indeed the construction with more pieces contributed to the better holding of the shape over the forefoot, where the orthopaedic shoes were prone to crease on the uppers above the metatarsal break.

5.5 DISCUSSION

Overall performance

This trial has brought together the expertise from two quite different manufacturers of shoes in order to transfer knowledge both of new advanced techniques and of the cosmetic styling so readily developed on the system. In order to make use of the CAD system and the expertise of the designers, it was necessary for the orthopaedic side to appraise the fashion designers of the medical and functional constraints on style. Also the pattern engineers needed to appreciate the methods of lasting which would be employed, quite different for the one-off orthopaedic shoe than for the fashion shoe. This exercise in communication has produced very positive results.

In a service situation, a CAD system would not be efficiently employed in the manner of this trial. However this trial confirms that an existing CAD shoe upper system has the technical capability to design patterns for at least some categories of orthopaedic shoes. The system generated patterns which were a good fit to the orthopaedic lasts. Minor problems such as that which arose with lining allowances can easily be rectified in future. The system could also benefit from minor developments for orthopaedic use, for example to expedite balancing. These will be discussed fully in a separate detailed evaluation of the technical factors.

In the investigation of the contribution of artistic design into surgical shoes for the improvement of cosmesis it was noted how up-to-date fashion in colour, materials, patterns of stitchings and punchings and in the style of accessories such as lacings, fastenings and eyelets etc may be incorporated into special shoes. This was shared by both sexes. Several children wished to copy their friends in having trainer-style footwear, which is accepted by most state schools for everyday wear. The design input was not able to influence shape of the shoes, which was pre-determined by the orthopaedic lasts. However, it was possible to use design style lines and other features to minimise abnormalities in shape and to suggest an alteration in the perceived appearance of the finished orthopaedic shoes. Good design also minimised the perceived differences between odd-sized feet.

The three cases where current Clarks designs were used are particularly significant. The psychological impact for a child to have the same style as those available to their

peer groups cannot be underestimated. This procedure of using a library style is the obvious mode of operation for a service scenario, and the CAD system showed that it was entirely feasible to map such a style over an individual last within a reasonable time scale and with good results in terms of the pattern pieces which were generated.

There were no problems of fit directly attributable to the CAD system for these patients, who were typical of two major groups of consumers of orthopaedic shoes. Although none of the deformities were gross - such as would absolutely necessitate the taking of a cast - these feet could not be accommodated within normal shoes without problems. Extension of the findings to cover other major consumer groups, eg. patients with arthritic conditions, is not automatic, although the team could see no technical reasons why this should not be possible. The functional requirements and medical problems should first be investigated to give the designers direction for possible suitable styles, but the last shapes would not be grossly different to those already encountered.

It was noted by the orthopaedic shoemakers and by the patients that the leathers used in this trial were of a very high standard and had a large range of colours and textures. This is due to the large quantities a volume manufacturer is able to buy, and is one of the benefits which might be available from more centralised production of shoe-uppers than is presently common in the UK. This incidental observation from the trial has cost-implications related to repair and replacement for the active patient.

The results of the technical evaluation are highly encouraging. Initial doubts as to the capabilities of a CAD system to operate away from the symmetry of the standard application, or to cope with shapes substantially different from those of normal lasts, have been dispelled. Obviously this statement must be qualified as to the limited range of last shapes which have been trialled, comprising those which can normally be dealt with by adaptation of a standard last. Further tests are indicated to confirm the capabilities for gross deformity where the last-maker would normally work from a plaster-cast of the foot.

The Design System

Both the transfer and the grading facilities were essential parts of the operation, although used in a different capacity than their normal function. In volume design, these facilities allow ranges of sizes to be developed over slightly different fashion shapes. In this orthopaedic trial a combination of grading and transfer was used to map existing styles onto the custom last, and to map original designs for odd-sized feet. The success of this operation is attributable partly to the ability to grade in three

dimensions. In the present system the procedure used was a transfer in 'real space', having graded the reference last for the style to a size close to that for the orthopaedic last before transfer. This process required several operations in the current Shoemaster system. It was however clear that these could largely be automated. Nevertheless, a combination of a parametric transfer of the main style lines, in combination with real-space transfer of styling features which need to be held constant in size (eg. features on the apron) would produce a more rapid result with less need for operator intervention.

The design process is inextricably linked to the availability of certain leathers, stitching techniques, accessories and punching which can be specified on the workstation. In this trial both the upper design and the cutting & closing of the uppers were done by the same team, ie at Shoemaster.

Development of extra facilities for orthopaedic usage are indicated in

- balancing: a facility to display both shoes on-screen during styling is needed to achieve the best balance in the design where the feet are of markedly different dimensions
- line of insert: the designer needs an indication on the 3D image of the location of any insert to prevent a faulty perception of where the foot is in relation to the style lines being drawn.
- indication of heel backseam and under-ankle height: these heights should be specified from patient measures, and a facility added to ensure that the top line passes through the appropriate points. Perhaps the line of the insert or insert allowance could be indicated on the last model.
- sole units: consideration should be given to addition to the library of typical soles provided by the orthopaedic footwear, and to communication of this information to the place of lasting and sole attachment.

There is obvious need for improvement of the flattening algorithm in the midfoot region where this is substantially different from normal. More experimentation is required to establish the particular conditions which gave rise to inaccuracies over the instep.

The ability of the system to produce low boots is under consideration.

Service Implications

The procedures used in this trial are clearly not feasible for commercial production, taking too much time. However the potential for development into a volume system can be noted. The first step involves the generation of a last model within the computer. Although in this trial the lasts were made by hand and then digitised into the computer, in a fully integrated system it would be envisaged that the last would be entirely computer generated. This would involve storing a data-base of basis last shapes within the existing library structure, grading the shapes to match foot measures, and then possibly making modifications on-screen. All of this is feasible with the existing software structure, particularly because the underlying parametric model offers facilities for surface adjustments. Alternatively, for existing hand-made lasts, a faster way to enter the grid of points is required; note that Shoemaster requires that a structured grid of points be entered to represent the last shape, which is not a trivial problem when starting from unstructured data from, say, an optical shape scan.

In service, it would not be feasible to consider making original designs for individual patients. This system has shown that styles held in a style-library can be mapped over the individual last as required and in a reasonable time. Further trials are indicated to assess realistic timings for this process. A number of the current high-street styles were found to be suitable in the children's ranges and the exciting prospect of providing fashionable shoes is a real option.

5.6 CONCLUSION

The results of this trial of a commercial computer-aided design system are encouraging for its potential use with orthopaedic shoes. Special features of the system can be adapted to meet the one-off nature of this application. An evaluation of the system shows its potential for integration into a fully automated system for design of both shoe last and shoe uppers, with projected extensions for the volume trade which would also be of benefit for the orthopaedic use.

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CHAPTER 6. INTEGRATED SYSTEMS

6.1 AN INTEGRATED APPROACH

To achieve a practical working solution from computer technology, it is essential to consider the operation of the whole system and not just the operation of component parts. A careful study of the topic of integration reveals several levels of integration which are necessary, and in this chapter these are developed in the light of the preceding work.

At the most basic technological level, integration might imply that the various hardware/software elements are able to communicate. This is largely a matter of protocols for data exchange between, for example, a shape scanner and the host workstation, or the workstation and a CNC machining device. Decisions must be taken at the design stage of the system as to the speed of data transfer required. At the most basic level, information may be transmitted as now on paper or 3-D model, which is then keyed into the CAD system at the destination. If a digital transfer is required, the required data transfer rate will determine the type of port through which the data passes and which standard 'handshake' to use (a convention so that clashes in transmission/receiving do not occur). These latter factors are generic to many computer applications and well understood by computer systems engineers, and will therefore not be further mentioned. Only the decision as to the benefits of manual or digital transmission will be probed.

Of more interest to the system designer than the interface protocols is the actual content of the data passed between and stored in the component parts of the system, and the information content which it conveys. For example, what information is needed about foot shape and pressure in order for the shoe design to proceed? The study of this aspect of integration can be divorced in the first instance from any hardware issues, and treated as an information technology problem. It is desirable to decide on the IT issues right at the start of the design of a computer-aided system, for it is from these requirements the specification of the hardware should flow. The reverse situation, where the availability of hardware influences predominates the information flow, is often the case, and this limits the conceptual design.

The final aspect of integration which must be considered a priori is the integration of the technological system within service delivery, including both the clinical and manufacturing facilities. Although some industrial CAD systems are introduced simply

as a direct replacement for one single activity (eg. the use^{of} a computer-aided draughting package to replace the drawing board), this is rarely the end point: the technology is enabling for other organisational developments and soon pervades many related activities (eg. electronic storage and transmission of drawings: automatic materials take-off, and so forth). The introduction of CAD systems for shoe design must be handled with due consideration of the desirable and likely effects on the whole delivery system. This requires an understanding of the strengths and weaknesses of the system at present, and an analysis of possibilities and needs for improvement, which has been described and probed in Chapters 2 & 3.

This chapter is thus a discussion of the design of CAD system with these latter two aspects of integration firmly in mind, ie. information technology issues and service delivery. The arguments arise from consideration of the work of the preceding chapters on various aspects of detailed parts of the system.

6.2 COMPONENT STAGES AND INTERLINKING

Identification of the Stages of the Process

The integrated approach requires that all aspects of the system must be analysed and considered. The stages will now be identified. After a hospital consultant has prescribed bespoke shoes for a patient, there follows a sequence of actions which involve both the clinic team and the technicians at the orthopaedic shoe manufacturers. Assuming a common model, a typical sequence for bespoke shoes with moulded inserts on a fairly normal footshape is described in Figure 6.1. This model is made following observations at orthopaedic companies as preparation for the trials described in Chapter 5. In this case, the shoes are to be made from measures and not casts, although a slipper cast is taken for the manufacture of the moulded inserts.

STAGE	OPERATION	HOW	WHERE and WHO	APPROX TIMING
1	Foot measurement and shoe specification	Length, height & girth measures, with plan outline taken. Plantar plaster casts made for insoles. Inked mat for pressure map	<u>Clinic:</u> clinician & orthotist	Week 0
2	Last making	Using foot shape measures to modify an ex-fashion last	<u>Manufacturer:</u> last-maker	from Week 1
3	Insole making	Using plaster cast and/or inked impressions	<u>Manufacturer:</u> specialist	-
4	Pattern design and cutting	Made to the last shape (with allowance for the insert 'blocked on')	<u>Manufacturer:</u> pattern cutter	to
5	Trial shoe fabrication	Shoe 'rough finished' ie. upper tacked down onto sole Dispatched to clinic	<u>Manufacturer:</u> fabrication technicians	Week 7
6	Fitting	Fit the trial shoe, noting down any modifications required on chart: Dispatched back to manufacturers	<u>Clinic:</u> orthotist	Week 8/9
7	Modification & finishing	Modifications may be made -to the last - to the shoe upper - to the insole/sole Finishing off shoe Shoe dispatched to clinic	<u>Manufacturer:</u> last-maker, pattern-cutter & fabrication technicians	week 9/11
8	Delivery	Fit the finished shoe Acceptance by clinician	<u>Clinic:</u> orthotist & clinician	week 10/12

Figure 6.1 A typical flow of work from clinic to manufacturers.

There are many variants on the above pattern. In foot measurement, some companies prefer to take whole foot casts for reference: most do not take any form of pressure

measurement in the UK. Some orthotists return to their manufacturing base at the end of each day or each week to hand in their charts: others may post these in. In last-making, the starting point may be a stock orthopaedic last rather than one of a batch of redundant fashion lasts, although this is rare in the UK, and the insert allowance may be included in the design of the last rather than blocking the insert onto the last. Pattern cutting may be put out to a second company who specialise in just that activity, and who would return the closed upper for the given last and style. Fabrication of the shoe demands several skills which might be carried out by one man in a small company, or by several different workers in a larger facility. A trial shoe fit is normally carried out for a new patient or where major design changes have been made, but could in certain circumstances be forgone. Depending on the clinic arrangements, the patient may not be recalled for fitting until the shoe arrives in the clinic, thereby adding another week to two weeks delay in the process. Depending on the severity of modifications needed, there may be a second (or more) cycle of trial fitting before the shoe is finished for delivery, again adding a few weeks to the overall process.

The suggested timings reflect an average transport of a completely new order through the process at a UK manufacturers. These timings may vary considerably for an individual patient's requirements. The process for repeat orders (ie. where an existing last and patterns exist) may be shorter, and for a complicated order (for example for shoes made to casts with extra features such as raises or external calipers) may be longer.

Critical Stages for Information Transfer

Two critical areas are identified by orthopaedic companies where transfer of information limits the fit quality:

- stage 1 to stages 2,3&4: transmission of the initial specification from the clinic to the shoe manufacturers
- stage 6 to stage 7: transmission of the modification requirements following trial fit from the clinic to the manufacturers

Additionally, another area is often identified which often produces problems

- stage 1 to stage 8: transmission of reasonable cosmetic expectations from the orthotist to the patient

To deal with this list in reverse order, it is known that the patient may reject the shoes on cosmetic grounds even when the fit and function are adequate. This is often said to

be the result of 'unreasonable' expectations on the part of the patient (although by what criteria the expectations are unreasonable is unclear). If the patient expects to look 'normal', then this may be impossible because of deformity or orthopaedic requirements for extra-depth shoes or adapted outer soles. However if the patient is requesting that the shoe styling is up to high-street standards and in fashion, the trials of Chapter 5 indicate that this is technically possible: although it may not be economically feasible with current craft techniques. A key factor may be the element of information and choice for the patient at the initial consultation. Offering a choice of colour and style verbally is not enough. This has been recognised by several orthopaedic companies, who now have put more effort into the production of a catalogue to show examples. However there is still a problem that the patient cannot envisage what the shoes for their own condition will look like, and many of the catalogues show shoes made over normal lasts.

The second area is that of accurate transmission of the requirements for modification of shoes following a trial fit. In many cases the modifications may be relatively minor and a written descriptive note is adequate to allow an exact correction. However there are many cases where a fairly major modification is required, which is not surprising given the complexity of some foot problems. From trial fit of the shoe, the orthotist has to convey instructions which may result in the alteration of both the last and the patterns. He may do this by suggesting increases/decreases in certain measures of the last, or additions/subtractions of material from the shoe upper in certain areas: or he may indicate a problem area and leave the detailed interpretation of the adjustments required to the manufacturer. Such instructions require a great deal of skill to formulate in order to achieve the desired result on the finished shoe, and also depend on the consistent interpretation of the last-maker & pattern cutter to adjust other 3-D and 2-D shapes to match the measures.

The major area where information transmission is critical is that of the initial specification. There are probably two issues here, namely the reliability and the adequacy of the current system specified in BS 5943. Reliability can be addressed in terms of validity and repeatability of the measures: are the measurements taken as specified really a valid measure of the part of the foot indicated, and can the measures be taken repeatedly with the same result? On the other hand, adequacy of the system questions whether the measurements specified are sufficient to describe the foot for the purpose of shoemaking. Both of these issues are obviously queried in the orthopaedic industry, and there is evidence of attempts to overcome limitations by novel methods. For example, different measurement systems and techniques have been observed to be in use, including various foot measurement gauges (eg. the proprietary Brannock

stick, and the Ken Hall tape system), and modifications to the methods of recording girths by altering the locations.

The initial specification also requires a description of the pathology, although this section is often not filled out on the charts. From discussion with orthotists, it is revealed that the orthotist will use his knowledge of the foot pathology in order to determine the shoe style and any specific requirements for inserts, which are then explicitly detailed on the chart, thereby obviating the need for this information to be conveyed to the manufacturer. Discussions with the technicians at the manufacturers has not revealed any decisions which take pathology into account, but it may help the last-maker to understand the instructions being given. It has not been possible to discover any written procedures or authoritative consensus opinion which details the design of shoes for a particular condition. Several opinions have been found in books, reflecting the views of a single author but without general acceptance indicated either by their adoption in the schools or general widespread use.

Very few UK orthopaedic companies use foot pressure maps in their specification for footwear. Some use is made of pedobarographs in specialist centres, primarily to understand the diagnosis prior to specification. In continental Europe, the maps are limited to inked-mat prints of the foot flat on the floor, and these are primarily used as a visual reference to provide local relief for high pressure points, plus perhaps an indication of where anatomical structures lie within the plan outline. This poor integration of pressure information into shoe making could be ascribed to the lack of fundamental understanding of its interpretation (as evidenced in Chapter 3): to limitations of technology to barefoot imprints which are of limited value in designing shaped insoles (addressed by the new flexible insoles but still in need of further development to be reliable and economic) : or to a traditional separation between the role of the shoemaker and the orthotist, with pressure maps of more use in the orthotic manufacture.

^a Critical Stages for Transport of Materiel

It can be seen that the manufacturing process involves both several stages of physical transport of materiel (physical goods and materials) between clinic and manufacturing facility. Since speed of production of footwear is one of the critical problem areas identified by both patients and clinicians, the possible reduction of delays in an integrated CAD system should be explored.

(i) Stage 1 to 2: From measurement and casts from clinic to manufacturers.

Clearly there may be delays of the order of a day to up to one week introduced at this stage. Electronic transmission of the measurement charts is possible now (by fax) for the majority of orders if desired: only one day is needed to post the measurement chart back to base. Slower physical transport of plantar casts would not influence the overall manufacturing delay, because this is not a critical path in the shoemaking process: the insert manufacture can proceed in parallel with last making. In the current UK system then with overall delivery times of more than two months, there would be little gain in digitisation of the measurement information to allow for transmission by modem, for example.

(ii) Stages 2 to 5: Within the manufacturing process up to trial shoe delivery

Although the manufacturer is allowed a guide time of 6 weeks to complete this stage under the national contract, the active time spent in the various constituent processes is far less than that. Last-making may take for example about 1 hour: pattern design might be completed in less than 30 minutes: cutting and closing the uppers might likewise take an hour: and the stages of fabrication and adding the outer sole take less than 1 day in total. In fact, a pair of shoes could be produced in a few days. In practice, the manufacturer may be hard-pressed to meet the guideline. The issue here then is not the time that each process takes, but efficient usage of manpower and plant. In order to meet contract costs and quality standards, the jobs may be batched in some way, and there must always be a supply in order that technicians are not left idle. With a varying workload, this necessarily results in delays.

(iii) Stages 6 to 8: Trial fitting and subsequent modification

An appointment for trial fitting may not be made until it is known that the shoe is ready, because of the difficulties in prediction of the availability of the shoes. Because the delivery is made at a clinic which often may only be running at fixed weekly sessions, this produces a significant delay. Subsequent returns to the factory and back to the clinic all introduce their own significant transport and waiting time delays.

6.3 TARGET AREAS FOR SYSTEM IMPROVEMENTS

Initial Specification

The benefits of any improvement in this area can be substantial, leading to improved quality of fit and function through better last, insole and style design, reductions of weeks in the service delivery by potential elimination of trial fitting stages, and reduction of costs of rework. The problems have been identified as repeatable acquisition of an adequate foot shape description: use of foot pressure data: and a systematic approach to shoe prescription related to pathology and function.

There is very little written of a scientific nature on the subject of foot measurement or assessment and there is no consensus guideline available on shoe prescription. Target areas should be:

(i) Reliability and validity of existing foot measurement systems.

Quantitative studies need to be performed on reliability of existing systems. Cross reference between the measures of different systems might be used to explore how valid some of the measures are by, say, comparing the results for joint width or girth taken by different techniques. Furthermore the differences caused by non-weightbearing, partial weightbearing and full weightbearing need to be quantified: only confidential reports of this data have been obtained. Indeed it is possible that the extent of shape deformation during weightbearing can be used as an assessment of flexibility of the foot, and may be taken into account in the shoe design.

(ii) Analysis of information requirements for future CAD systems.

This involves making a match between the information input to the CAD system, and the information required to operate the system. Although this seems obvious, there may be a tendency to capture too much data from a comprehensive shape scan or complex pressure mapping system, without the possibility to use this at a later stage: or alternatively, the CAD system may have to make assumptions where a few simple measurements could have provided a firmer specification.

(iii) Foot measurement hardware.

It is probable that even a modest investment in equipment for foot measurement could produce more reliable results than the basic tape measure, pen and paper

method currently advised in BS 5943. A variety of alternative devices have been noted in use at a limited number of centres, including the use in the Netherlands of a slightly modified zerox machine to record the foot outline with any surface features (ulcers, etc) of note. However the development of the hardware must be subservient to the analysis of (ii) above: and should be made in the light of appraisal of current techniques.

(iv) Development of guidelines for prescription vs. pathology .

The development of quality manual for the prescription of orthopaedic shoes is entirely in line with other quality initiatives in the health service, and would allow for a more accurate specification of the footwear requirement to be matched to audit of the outcome. The adoption of CAD systems, if correctly managed to eliminate random manual intervention, facilitates the process by providing a reproducible recorded interpretation of the specification.

(v) Studies of biomechanical factors which affect shoe specification.

The work of Chapter 4 into rigid insert design is a small part of the fundamental knowledge which could be employed in this area. Of particular note is the relevance of shoe and orthosis design to the arthritic patient, where the changes in alignment caused by even minor adjustments to the foot orientation and function can provide miraculous relief of pain, or conversely totally debilitating pain, up through the lower limbs and the spine. Again, although individual orthotists have their own policies for treatment of such pathology, there are few quantitative ways to incorporate this into shoe design.

(vi) Studies of efficacy of existing designs of shoes and shoe inserts relating to plantar pressure distribution .

The work described in Chapter 3 highlights the multi-faceted aspects of measurement and interpretation of stresses under the feet. Far more clinically directed work is necessary in order to define the requirements for modification of these stress patterns, and to translate these requirements into shoe and insert designs.

Additionally, the psychology of the cosmetic and functional choices offered to the patient could usefully be explored in parallel. CAD systems in theory enable the patient to have a good impression of the style over their own lasts before any manufacture commences.

Last Design

The shoe last is the ultimate determinant of fit of a shoe, since it determines the space within the shoe. The characteristic features of lasts have been developed over centuries for the volume trade, and last design and making is an established and documented skill in that trade. The Shoe and Allied Trades Research Association (SATRA) for example offers a last assessment service which would be used by last manufacturers to ensure standards of characteristics were maintained in a new range. Often a small deviation from an acceptable ratio of variables can result in shoes with poor fit characteristics. This may be picked up during the extensive trial fitting evaluation which volume shoe manufacturers employ, else it will result in poor sales as the line is on average rejected by customers.

In the present orthopaedic trade, the last-maker starts from a basis last which may be well-removed from the final shape which he requires, and then proceeds to adjust the shape with reference only to the limited measures of the foot. This requires a great deal of skill to maintain acceptable last characteristics. Additionally, the last is not made as an exact match to the foot measures, but a system of 'last allowances' (ie. differences between specified foot and last measures) is employed. Suggested last allowances are not available in published literature, and initial discussions suggest that they vary from company to company, are not used consistently, and are adapted for individual orthotists to compensate for tendencies to measure loose or tightly. 14

The target areas in last design should therefore include a study of the influence of basis last choice on the final design, formalisation of last allowances, development of a system of last assessment.

Pattern Design.

The pattern design affects both the function of the shoe and its cosmetic appearance. At present the designer must interpret each written instruction into a unique set of patterns. This hand-craft process introduces several limitations compared to the volume trade, where a thorough evaluation of the pattern design is made. Limitations may include restriction to simple designs to contain design time, restrictions on styling features near to the tread-line because of the large edge allowances used, limited use of automated machinery for the same reason, poor control of material stressing during pulling of the upper over the last leading to excess material (as noted in the pilot trials where the upper creased excessively) and uneven surface finish.

The target must be to introduce CAD technology which allows for style libraries of known characteristics to be available for 'mapping' over the individual last. Also, specific features of designs should be quantified for functionality, eg. providing sufficient opening for donning and doffing, and providing designs which minimise the cosmetic disadvantage of deep, wide or rocker-bottomed shoes.

Work Flow at Manufacturers

The organisation of an economic workflow through the manufacturers is a limitation on the delivery service. The use of machinery to ameliorate any bottlenecks would enable the average transmission time through the factory both to be reduced and guaranteed. This effect can be achieved in several ways

- by assistance to reduce the time per item spent by the craftsman
- by flexibility to absorb peaks of workload
- by automation to reduce the dependence on skilled manpower
- by integration of stages where waiting time might occur

The target areas for such automation must be where the most skilled craftsmen are employed, ie in last making and in pattern cutting. Ideally these two stages must be combined into a CAD system.

Trial Fitting and the Use of Shell Shoes.

The time to trial fitting could be reduced by the adoption of 'shell shoe fitting'. In this process, used in continental Europe and now being tested in the UK, a plastic vacuum-formed shell is made over the shoe last. This forms a shell shoe which is then tried out at the clinic. The use of shells has several advantages: the shell can be made as soon as the last and insert are available, which reduces the delays to fitting trial by approximately half: the shell is light, cheap and easily transported: the transparent material from which the shell is formed allows the orthotist to see where the shoe is tight and to mark locations directly onto the shell: and finally, the use of the shell allows the last to be corrected before any leather is cut, giving less time spent in reworks of the upper and sole. The disadvantages are that the patient cannot walk normally when trying on the shells: that the shell only assess the fit factors which are due to the last shape, and not those which are due to shoe fabrication: and that the outer soles are not precisely those which would be used.

An in-depth investigation of these factors has been initiated as part of a PhD study supervised by the author, and undertaken by postgraduate student R C Chen at King's College School of Medicine & Dentistry (commenced 1991). In this study, 15 volunteers from the staff of Clark's Shoes, all women, were used to compare the fit of either a pair of stock Clarks lace-up shoes with that of a pair of shell shoes made over the same last. The fit assessment was made according to a detailed protocol by Chen and a member of the Clarks Fitting Department staff (who is experienced in assessing fit characteristics before new models go into full production). Fit was categorised into five grades, with good at the middle, slightly tight or loose on either side, and unacceptably tight or loose at either end of the scale. Preliminary results indicate that shell fitting is comparable with normal shoe fitting for these normal foot shapes in all areas except the heel (Lord, Chen & van der Zande 1992). This technique is acceptable to orthotists in the UK. The introduction of this technology and the training of orthotists is therefore a target area.

6.4 CAD SYSTEM DEVELOPMENT AND EUREKA PROJECT 'SELECT'

Formation of Project 'SELECT'

In early 1991, the Eureka directorate of the EC organised an anglo-dutch 'brokerage' meeting on medical technology. The objective was to identify suitable projects for support under the Eureka scheme. One of the topics identified in advance as a possibility was orthopaedic footwear, and the author was invited to organise and chair a Working Group on this topic at the meeting. By June 1991, Eureka Project 661 'SELECT: integrated data-bases and CAD system for orthopaedic footwear' was formally adopted, with the author as the international director (see information leaflet, Appendix III).

The Eureka framework facilitate a close working relationship between the orthopaedic shoe industry, the volume shoe industry, research institutes and hospital clinics, and thus provides the appropriate milieu for service-oriented research and development. Furthermore, in the UK the work is partly funded through the Information Technology Directorate of the Department of Trade and Industry, placing an appropriate emphasis on information rather than manufacturing technology.

The first year of SELECT commenced in late summer 1991, and constituted a feasibility and definition phase. Evaluation of the subsequent report enabled the main 2-year research and development phase of the project to be commenced in November 1992. It is anticipated that at the end of this time, there will be functional models of the system in operation at orthopaedic factories in the UK and the Netherlands.

Outline Plan

The system envisaged at the outset was presented by the author at the workshop as a block diagram, figure 6.2. It was intended to be based on the Shoemaster system, which had already been used in pattern design trials (Chapter 5). During these trials, it had been established that the 3-D capabilities would allow close integration of last and pattern design, and that although the volume system was not currently developed for last design, it had always been structured with this in mind as a future development. The outline process includes digitisation of the feet, selection of an appropriate basis last, customisation of the last, and pattern design. As an alternative to last generation in the CAD environment, the option exists to input the shape of an existing hardware last.

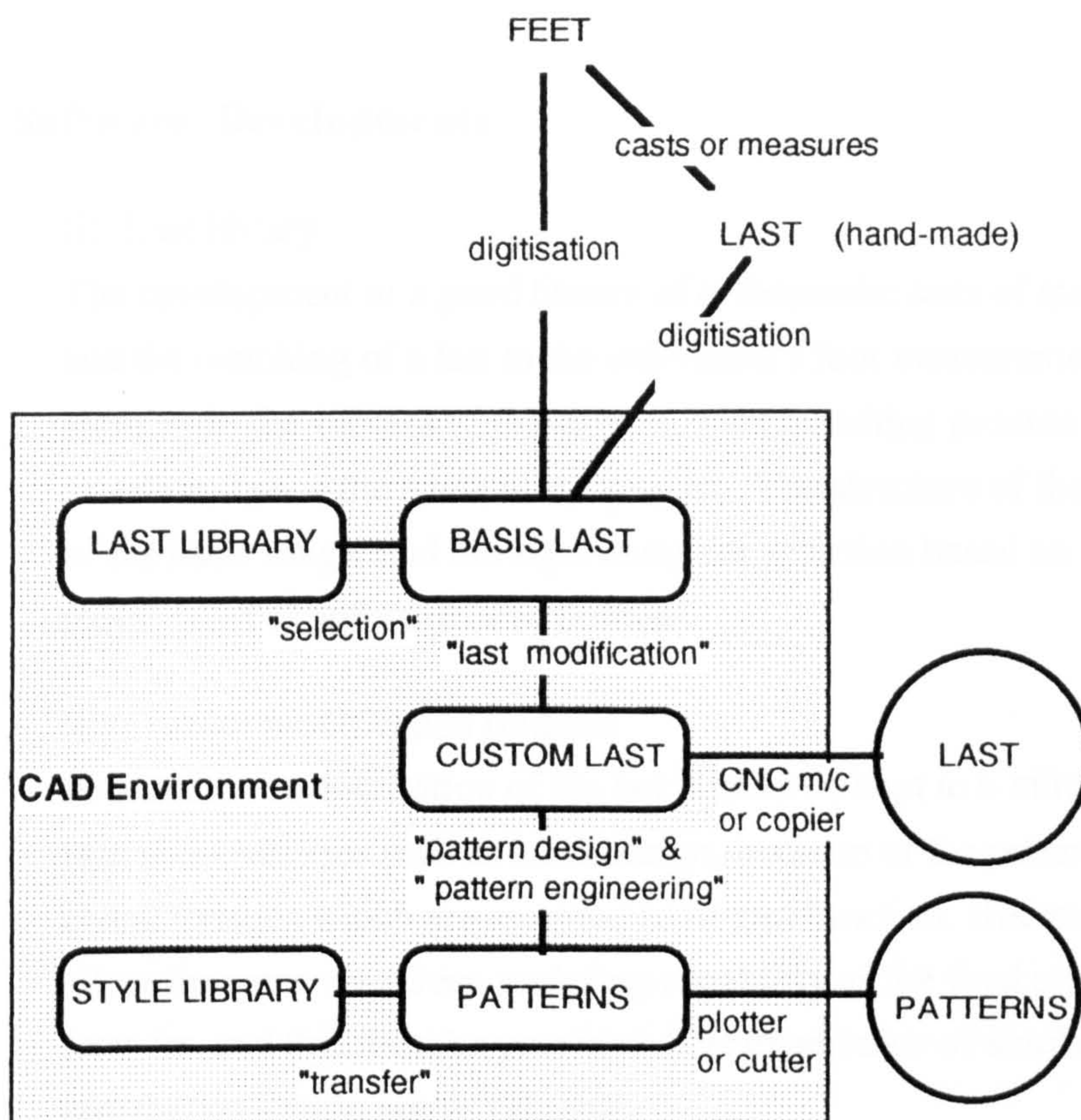


Figure 6.2. Outline plan for an integrated last and pattern design system.

The CAD system follows the 'reference shape' philosophy as described in the introductory chapters with reference to prosthetic socket design, in the sense that a library of suitable lasts for orthopaedic usage will be held in a data-base. The scaling of these lasts to the correct size for the individual can be done by the grading algorithms normally used to obtain a size range from a single model in the volume trade: these are well developed and tested. The alternative philosophy, that of transformation of foot shape into last shape, was discounted as the transformation is not sufficiently known despite years of research within the volume trade.

At this stage, it was decided that pressure information would not be explicitly used in the system because of the lack of consensus on its interpretation for purposes of shoemaking. Insoles would continue to be made by the conventional method, which includes the use of casts and inked-mat imprints: the CAD system would make provision for sufficient space by the addition of a thickness over the bottom surface of the last.

Software Developments

(i) Last library.

The development of a good library of orthopaedic lasts of quantified characteristics and the matching of a last to the individual's foot measurements are seen as the vital element in the success of the system. This matching process is described as one of selection: hence the name of the project. The structure of the last library, the choice of the basic range, and the algorithms for selection based on foot measurements are major areas of software development.

(ii) Custom modification routines

Subsequent customisation of the last should be kept to a minimum to accommodate foot abnormalities such as local bumps, because of the potential to lose the shape characteristics which are essential to fit and function. However it is necessary to allow for some on-screen sculpting capability as the final resort for unusual features, and this must be provided. The experience of similar applications in prosthetics should prove valuable.

(iii) Style transfer

After completion of last design, pattern design can be carried out by the style transfer process discussed in relation to the trials of Chapter 5. A number of special developments will be needed in this area also, as previously identified : display of two feet and balancing facilities: refinement of the flattening algorithms for high instep lasts: and development of a combined transfer in real space and parametric space, linked to anatomical marker points on the last, in order to hold certain styling features constant (ie the vamp styling details) whilst other features map to the outline of the particular upper. This process was described briefly in Lord, Smith and van der Zande (1992).

Hardware Developments

Hardware requirements include a foot digitisation system, possibly a last digitisation system, pattern cutting machinery and a CNC last making machine.

(i) Foot digitisation.

Within the integrated system, the requirements for the foot measurement system are that sufficient reliable data must be acquired to enable the selection of the best-match last. It has already been noted that in the parallel development of a CAD system at LIC Orthopaedics in Sweden, a full optical shape scan of the foot is taken, capturing 4,000 points on the surface of the foot: considerable resources have been employed in the development of this scanner. These surface coordinates are then reduced by a smoothing algorithm, and ultimately the standard girth and length measures are extracted: this set of measures, together with a plan projection are then used to scale a basis last. In effect, a very expensive scanner has been used to obtain the same BS measures which could be made by hand: what then are the advantages? The greatest of these is that the method is non-contacting, and therefore no distortion is introduced by the application of a tape measure or suchlike instrument. This ensures that the measures can be taken reproducibly, and answers one of the identified targets for improvement. Other advantages include the rapid data capture, and the full foot shape for reference (not at present used in the system). The counterbalancing disadvantage is the cost and size of the scanner, which severely reduces the number of clinics which can be economically serviced.

In project SELECT, it has been decided initially to concentrate on improvement of a hand-held device to obtain a limited set of measures directly from the foot.

(ii) Last digitisation.

The hand-held stylus digitisation method used with Shoemaster in the volume trade is time consuming, but has the advantage of producing a grid of structured data to which the surface model can be fitted. Optical scanning by a light-triangulation method is more rapid, but produces an unstructured cloud of surface coordinates. Mechanical contact digitisation by a spiral pathway would be subject to similar lack of structure. The unstructured data must be reduced onto a structured grid for conversion into the parametric representation central to the Shoemaster system. In this task, it is necessary to identify very accurately the feather edge which is a sharp transition between the upper and sole in the forefoot region, and to parameterise the two surfaces correctly. The development of such algorithms must be a priority for software engineers wishing to capture last shapes from an optical scan for input into this type of pattern-generating software. Work in this area is already reported by

Lord and Travis (1990) and formed the substance of Travis' doctoral thesis (1992) which commenced under the author's supervision.

(iii) Pattern cutting.

Pattern cutting is already available in a choice of technological levels, from outputting to an x-y plotter, cutting card patterns on a modified plotter, and directly cutting leather by water-jet or laser.

(iv) CNC last-making machinery.

At the end of the process, the CNC machine currently interfaced with the volume CAD system is a standard industrial mill which takes several hours to produce a model last. Such lasts are of high accuracy and good finish. The model last is then transferred to a traditional last-copying machine which can turn out a production copy in under two minutes. Although this process is suited to the volume trade, it is obviously unsatisfactory for the orthopaedic trade.

An alternative lower-cost method referred to by Duncan and Mair (1983) as polyhedral machining is employed in the LIC system ; this method, involving the slow rotation of a blank in a lathe while the milling tool moves radially and slowly traverses in a spiral path along the blank, has been adopted commercially for generation of moulds for prosthetic sockets in a similar application . However the process is still fairly slow, over 20 minutes per model, to obtain a surface finish and accuracy demanded for commercial shoe work. Fortunately, more than one commercial company has already demonstrated it is possible to retro-fit the traditional last-copier with a CNC input stage, and to produce custom lasts to high commercial standards in a reasonable time of under ten minutes. Preliminary trials have confirmed the compatibility between the output of the Shoemaster CAD system and such a CNC last-making machine. The retro-fitted lathe is available commercially although its cost is as yet high (approximately \$125,000): further reductions are expected as the uptake of such equipment increases.

The Future

Under Project Select, the development of a CAD system is progressing, broadly based on the above deliberations. Integration of the system, as developed in this chapter, is seen as a vital part of the development. The emphasis is on a pragmatic solution which will be flexible to cope with the different manufacturing and service delivery models used in the partners countries, with maximum utilisation of available hardware and software for economically feasibility.

6.4 Addendum

ADDENDUM (September 1993): Progress to date* :

The first year of project SELECT comprised a feasibility study and definition of the exact CAD system required. The team at KCSMD completed workpackages on basic information studies, case studies and foot measurement systems.

Information studies: Information studies were designed to provide a background of the service requirements, and to reveal differences between the procedures used in the UK and continental Europe. The system of service provision, manufacturing procedures and orthotist training in the UK was documented from working knowledge of clinical service, literature review, communication with the NHS Centre of Responsibility for Orthotics, and in-depth interviews and observation conducted at each of the four contributing UK contractors. A parallel study was conducted in the Netherlands.

The studies indicated a UK service which is undergoing major changes, including changes in contractual arrangements with the contractors, redefinition of the roles of consultant medical staff and other hospital staff involved in footwear provision, and increasing use of stock orthopaedic shoes. The studies at the contractors showed some significant differences in practice within the UK (with respect to the possible implementation of CAD technology), but also a willingness to embrace standardisation in these, provided that this could achieve a better quality product at no increase of cost. A more significant difference was noted between practices of the UK and the Netherlands companies, particularly in the dutch use of shell shoes. The higher price of shoes on the continent was reflected in more time-consuming methods but higher achievements in pattern design.

Case studies: The purpose of these studies was to quantify the relationship between measurements of a number of feet and those of the orthopaedic lasts produced for each of those feet. This was approached by a retrospective study of the foot measurements and corresponding last measurements of existing patients who had been issued with orthopaedic shoes. The studies indicated wide ranges of 'last allowances' (the differences between last and foot measurements) which resulted in a satisfactory fit. However, the wide range did not necessarily imply a wide tolerance; factors other than the normal measurements are significant in defining fit, including last style, shoe style, foot mobility, foot pathology and individual preference. Another factor is the variability of foot measurements taken by the BS5943 method previously described. These conclusions were reinforced by the simultaneous work of Chen (thesis recently successfully defended[#]) which also showed wide ranges

* The work under the Eureka project, jointly funded by the DTI, is covered by a business agreement which stipulates commercial confidentiality: detailed description of the trials and results may not be published. However a brief synopsis of the work carried out by KCSMD as a partner in this project is given.

[#] Chen R C C. An investigation into shoe last design in relationship to foot measures and shoe fitting for orthopaedic footwear. PhD thesis, Univ. London, August 1993.

6.4 Addendum

of last allowances even for normal subjects without foot pathology. Our conclusion was that, with the present state of knowledge, it is not possible to define the definitive shoe last for an adequate fit based on standard BS5943 measurements alone. A trial fit is still needed, although improved understanding of the relationship should gradually reduce the proportion of trials which result in major re-work on the last or shoe. The workflow through the CAD system must acknowledge this requirement.

Foot measurement studies: The range of measuring devices used in orthopaedic practice was described and the basic information content from these devices compared. Additionally, inter-and intra-observer tests were conducted to determine the extent to which the lack of first-time fit of a shoe is due to unrepeatability of the foot measurements. The results indicated areas in which measurement techniques need to be improved and standardised. The variations were not sufficient alone to account for the wide ranges of last allowances noted above. This work forms the basis of the specification of the measurement system required for the CAD system.

The second phase of project SELECT commenced in November 1992. M Lord remains the UK Director, and the role of international coordination has now been passed to the dutch group TNO. The KCSMD team are primarily involved in the development of a benchtop last digitiser, required as described on page 183: and also form a major contributor to the specification and testing of the style transfer software to be developed by C & J Clark.

Benchtop last digitiser: The target is to produce a working model within one year. Specifications have been drawn up, the conceptual design and feasibility study is complete, and hardware fabrication/software implementation is in progress on a laser-based scanning unit.

Parametric style transfer: A second major area of contribution is in style transfer. This part of the work is funded in part by a grant from the Arthritis and Rheumatism Council which supports a professional shoe designer on the team. The researchers are contributing to the definition of key reference points and associated parametric transfer procedures. Additionally, protocols have been developed for testing aspects of pattern design and style transfer by a parallel study to the equivalent manual process in the regular workflow at the contractors. Libraries of styles are also being developed on the CAD system, conforming to the styling standards observed in the dutch practice.

The other SELECT partners are contributing development of surface modification software, parametric transfer software, foot measurement devices, a last library, and interface design to CNC machinery. A working demonstration of the system is projected at the end of the second year, following trials in each of the two contributing countries.

CHAPTER 7. CLOSING COMMENTS.

This thesis is a contribution to the continuing development of technology to assist in design and manufacture of orthopaedic footwear. It has probed several different aspects of such a development, all of which are necessary to harness such technology into a practical and fully functional system. As laid out in Figure 1.9, some of the chapters present completed work, and others relate to the initiation of future studies under the author's supervision. (p50)

In Chapter 1, the background to the multifactorial aspects of shoe design was explored. The service delivery model was explored as the setting into which a CAD system must be imposed. Many different service delivery models can be found, using different processes for manufacture of the footwear from fully bespoke through stock shoes to adaptations of patient's own footwear. The emergence of CAD as a tool for design in this and related fields was probed with particular attention paid to the application of computer-aided design for lower-limb prostheses, where the experience of much research effort over the past decade has allowed different philosophies of approach to be observed. In addition the problems of the foot requiring orthopaedic footwear were described.

In Chapter 2, a survey of clinicians regarding their own experience and practice in footwear provision was reported. The survey complements others which have been directed more towards the patient as the consumer, and asked questions which are particularly related to the specifications for a CAD/CAM system. This showed priority needs for faster speed of delivery and improved quality, both in sense of 'getting it right all the time' and 'fitness for purpose'.

In Chapter 3, the thesis entered into the complex area of measurement of plantar stress as it relates to the design of footwear. Some of the problems of consistency of results from a welter of studies conducted in the past decade relate to the characteristics of the instrumentation. This chapter commenced by looking in detail at two technical factors relating to plantar pressure measurement, namely spatial resolution and threshold. The poor understanding of the limitations of current instrumentation caused by low resolution and high thresholds are shown experimentally to contribute to this current

lack of consensus on data gathered. Then three case studies were used to examine different aspects of pressure measurement : one relating to the effects of the presence of callous, one to the meaningful measurement of pressure under important metatarsal head region, and one to pressure measurement as an evaluation of shoe insole design. Finally a discussion of the contribution of plantar shear stresses is offered, proposing the importance of shoe design to the level of these stresses. Overall the work of this chapter demonstrates that there is as yet no consensus on methodology and analysis of plantar pressure which allows data to be standardised: and that there is still a long way to go to put a fully meaningful interpretation on the data. However, the third case study demonstrates that even the current understanding of plantar pressure can be used to evaluate aspects of insole design, provided that the data acquisition and interpretation is handled very carefully.

Chapter 4 presents an in-depth study of one particular aspect relating to the design of rigid orthoses. Usually a plastercast of the foot is made, and this is corrected by craft methods to reposition the foot. In this paper, the possibilities are experimentally explored to imitate in the computer the change in contours of the foot as the foot is rotated from its free position into the 'neutral' position for casting. The analysis elucidates where twist occurs naturally, providing information for subsequent algorithms to imitate the twist.

The development of a CAD shoe design system is a major undertaking, probably requiring investments in the millions rather than tens of thousands of pounds to achieve a solution which is industrially viable (rather than a bench demonstration). The most expeditious developments for orthopaedics will probably evolve from the existing systems already developed for the volume trade. Chapter 5 provides the start of such a process. This experimental work, the only published material known to date on this topic, opens up aspects of the suitability of the volume system and special orthopaedic requirements for the upper design part of the system..

Chapter 6 considers the development of a design brief for a complete integrated orthopaedic CAD Shoe system, based on the requirements developed in previous chapters. This has lead to the initiation of a Project SELECT under the Eureka initiative, which will undertake the task of development of this system over the period of 1992 to 1995.

The work of this thesis has stimulated several other developments, which are currently in progress. The direct outputs are

- studies of R Hosien on shear measurement (introduced in Chapter 3)
- project SELECT
- studies of R Chen on shoe fitting parameters (introduced in Chapter 6)

One final comment is offered. It is probably not the development of the hardware, which can demonstrate the operation of the measurement/design/manufacture stages in the laboratory, but the development of an integrated system which can be accepted into the manufacturing and delivery service which presents the major challenge for the introduction of computer-aided systems into shoe design. The emphasis needs to be on the information technology, clinical requirements and industrial aspects in the near future.

APPENDICES

APPENDIX I QUESTIONNAIRE FORM

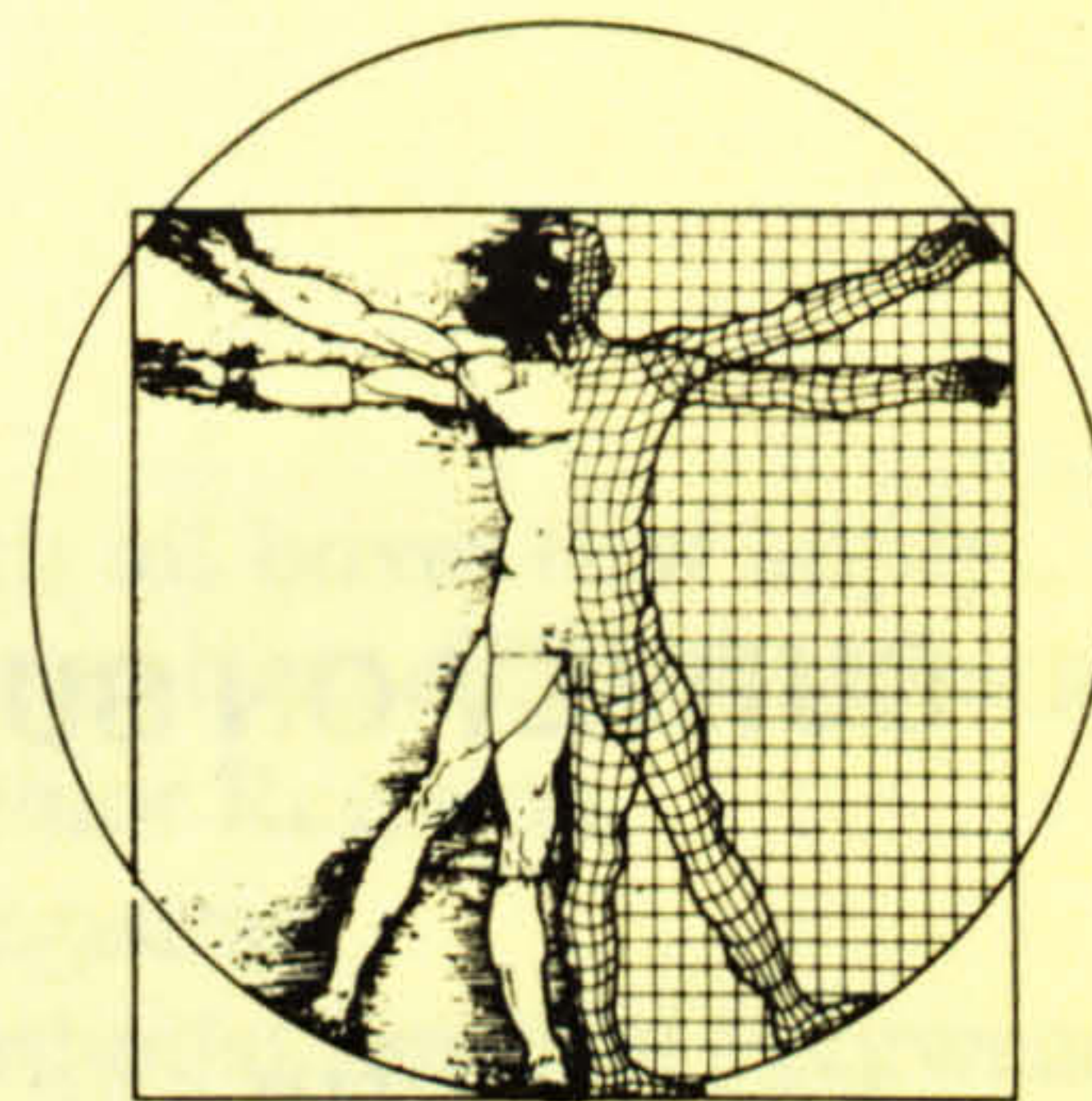
The following form is the questionnaire issued in the clinical survey described in Chapter 2.

APPENDICES

APPENDIX I QUESTIONNAIRE FORM

The following form is the questionnaire issued in the clinical survey described in Chapter 2.

King's College School of Medicine and Dentistry.
King's College London.



PRIME

Providing Research Into Medical Engineering

Department of Medical
Engineering & Physics
Dulwich Hospital.
East Dulwich Grove.
London SE22 8PT.
Telephone: 01-693 3377
Extension: 3031
June 1988

Dear Colleague,

Survey on Surgical Footwear

My team is conducting a major research project funded by the DHSS, which is aimed at the development of a computer aided design system to produce surgical or orthopaedic footwear. The project was started because of the large number of problems associated with the present supply of footwear to patients.

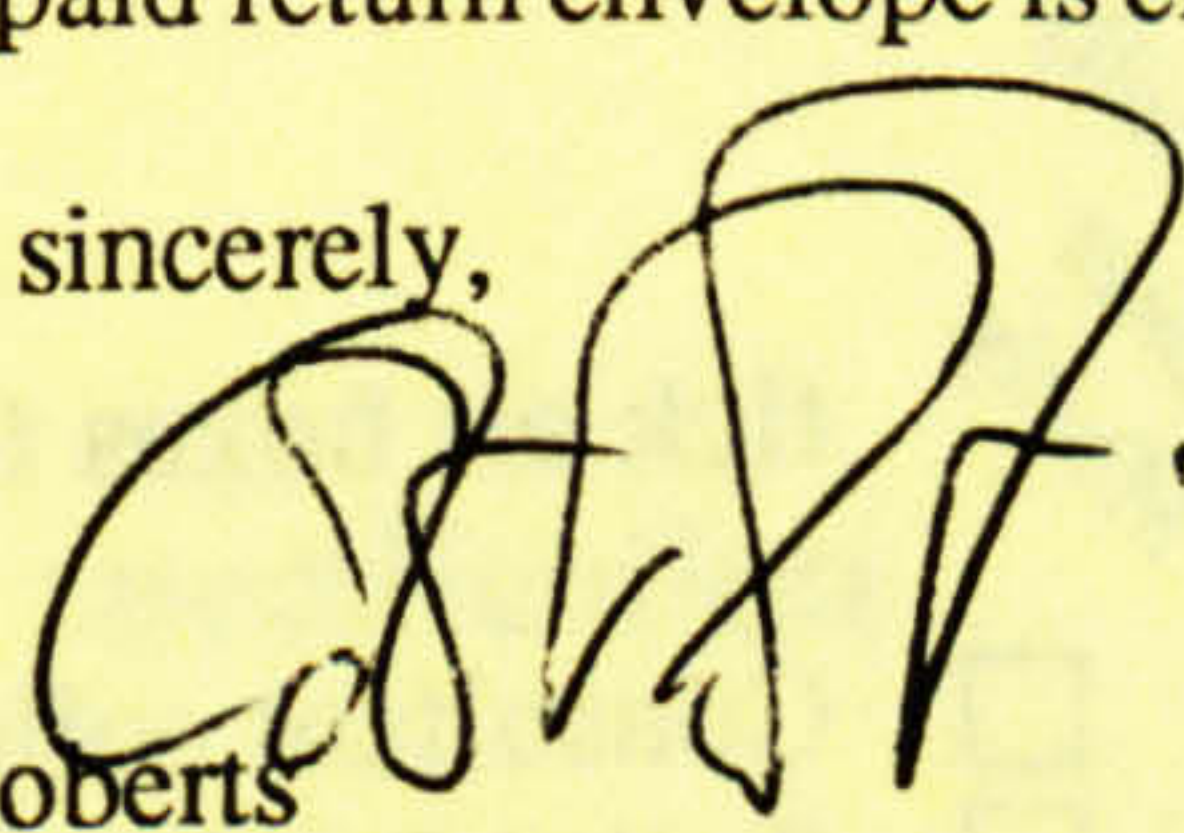
I ask for just a few minutes of that most valuable resource - your time - to give your impression of how the delivery system does & should work in your particular speciality and district. With limited funds it is imperative that we design something that will fit into the healthcare delivery system, which is the concern of this survey. Other survey work is being done to ensure that the research addresses the areas of greatest clinical need.

For your information, in the proposed CAD system a visible light scan of the patient's foot will produce a three-dimensional computer image which may then be rectified into an appropriate shoe last shape. The last will be produced in solid form and a shoe made on it in the normal way. This system should improve objective interpretation of the prescription repeatability and speed of delivery.

All information will be in the strictest confidence. No individual return will be identified in subsequent publication of findings.

A pre-paid return envelope is enclosed for your convenience. I thank you in anticipation.

Yours sincerely,


V C Roberts
Professor of Biomedical Engineering

Endorsed by

Dr Arnold Bloom MD FRCP Consulting Physician & Diabetologist

Dr Frank Dudley Hart MD FRCP Consulting Physician & Rheumatologist

Professor Leslie Klenerman ChM FRCS Professor of Orthopaedics

SURVEY ON SURGICAL FOOTWEAR - QUESTIONNAIRE

In strictest confidence.

For the NHS patients under your general care needing surgical shoes, inlays or modifications to existing footwear:-

Background information

- 1 In which of these categories do you have a substantial number of footwear patients?
- tick all boxes that apply..
- ☐ Children
 - ☐ Young adults
 - ☐ Middle aged adults
 - ☐ Elderly (> 70)
 - ☐ Normal active lifestyle
 - ☐ Slightly restricted lifestyle
 - ☐ Housebound
 - ☐ Bed- or chair-bound

- 2 Approximately how many patient consultations per annum **with you personally**, result in referral for foot wear, inlays or modifications?
- tick one box only
- ☐ 0-5
 - ☐ 5-20
 - ☐ 20-50
 - ☐ 50+

- 3 Please circle your region.
- | | | | |
|-------------|------------|-----------|-----------|
| N Scotland | Northern | NE Thames | Oxford |
| Grampian | Yorkshire | NW Thames | SouthWest |
| Tayside | Manchester | SE Thames | Wales |
| W Scotland | Trent | SW Thames | N Ireland |
| SE Scotland | W Midlands | Wessex | |

Organisation in your delivery system

- 4 Who first suggests that the patient may need these items?
- Very occasionally
Sometimes
Mostly
- tick all boxes that apply
- | | | | |
|--------------------------|--------------------------|--------------------------|------------------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Consultant colleague/yourself |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Senior Registrar |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Registrar |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Orthotist/Surgical Footwear Fitter |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Chiropodist |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Physio/Occupational Therapist |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Appliance Officer |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Other (please specify) |

- 5 Who sees the patient and makes the clinical decision that these items would be beneficial and justified?

Very occasionally
Sometimes
Mostly

tick all boxes that apply..

☐ ☐ ☐ Consultant colleague/yourself
☐ ☐ ☐ Senior Registrar
☐ ☐ ☐ Registrar
☐ ☐ ☐ Orthotist/Surgical Footwear Fitter
☐ ☐ ☐ Chiropodist
☐ ☐ ☐ Physio/Occupational Therapist
☐ ☐ ☐ Appliance Officer
☐ ☐ ☐ Other (please specify)

- 6 Who writes the technical specification of the item(s) for an individual patient?

Very occasionally
Sometimes
Mostly

☐ ☐ ☐ Consultant colleague/yourself
☐ ☐ ☐ Senior Registrar
☐ ☐ ☐ Registrar
☐ ☐ ☐ Orthotist/Surgical Footwear Fitter
☐ ☐ ☐ Chiropodist
☐ ☐ ☐ Physio/Occupational Therapist
☐ ☐ ☐ Appliance Officer
☐ ☐ ☐ Other (please specify)

- 7 Who checks the acceptability of these when they are issued?

Very occasionally
Sometimes
Mostly

☐ ☐ ☐ Consultant colleague/yourself
☐ ☐ ☐ Senior Registrar
☐ ☐ ☐ Registrar
☐ ☐ ☐ Orthotist/Surgical Footwear Fitter
☐ ☐ ☐ Chiropodist
☐ ☐ ☐ Physio/Occupational Therapist
☐ ☐ ☐ Appliance Officer
☐ ☐ ☐ Other (please specify)

Delegation of specification

- 8 To whom would you delegate as first choice the detailed technical specification for footwear, orthoses and adaptations?

tick one box only

☐ I would never delegate this
☐ Consultant colleague
☐ Senior Registrar
☐ Registrar
☐ Orthotist/Surgical Footwear Fitter
☐ Chiropodist
☐ Physio/Occupational Therapist
☐ Appliance Officer
☐ Other (please specify)

Perception of the service

tick one box only..

9 What do you think is the approximate cost of a simple pair of orthopaedic shoes?

- ☐ Under £100
- ☐ £100 - £140
- ☐ £150 - £180
- ☐ £190 - £220
- ☐ £230 - £260
- ☐ £270 - £300
- ☐ Over £300

10 If requested, could you name from memory the contractor(s) who supplies surgical footwear to your patients?

- ☐ Yes
- ☐ No

11 Are you generally satisfied with the speed of production of the footwear?

- ☐ Yes
- ☐ No

12 Are you generally satisfied that the footwear is suitable in practice for the purpose for which it was prescribed?

- ☐ Yes
- ☐ No

13 What is your overall level of satisfaction with the present system for the supply of surgical footwear?
(Room to comment below)

- ☐ Very satisfied
- ☐ Satisfied
- ☐ Dissatisfied
- ☐ Very dissatisfied.

If you wish to comment further on any aspect of the present footwear supply system, or on the system you would like to see, please feel free to write in the space below

Many thanks

APPENDIX II STRUCTURE OF PBG DISPLAY PROGRAMME

Modules and procedures

Unit	Externally-declared Procedures	Description
BTiffDA's	DoAbout	Displays info. on BTiff ownership
	DoDeskAcc	Loads desk accessories
BTiffInit	Initialise	Initialises its own variables, Sets up menus, gets strings and calib. values from resources, sets up main and info. windows, sets up image array
BTiffUtils	FSOpenFile	File opening
	FSClose	File closing
	SaveIt	Saves associated variables
	ClearData	Initialises flags, menus, variables after file close
	GetandDisplay	Reads file data into image array and calls display on screen
	ImagetoScreen	Displays image array as dithered image
	InitImageArray	Zeros the image array
	ChangeGain	Toggles between autoiris and fixed dithering levels
BTiffGraphics1	DoClickinDrawing	Decide where: in circle - drag or stretch.
	DefineCircle	Defines circle selected
	DrawCircle	Draws rubber-banded Circle
	DefineMarkers	Toggles markers on-off
	PutMarkers	Draws corner markers on circle
	ChoseFunction	Updates menu after circle function is chosen, and calls circle draw/delete

cont...

...modules and procedures cont.

	Dofunction	Either draws average info or circle profile info into info window
BTiffGraphics2	Mousecheck	Determines mouse position in drawing, and displays in info window
	SetUnits	For toggle between pressure/light & pixels/mm, sets flags and menus.
	Measure	Allows rubberbanded tape operation: returns start/finish of tape line, draws line and calls for info window update.
	DrawTapeProfile	Estimates pressure profile from start to end of 'tape', and draws in info window
BTiffGraphics3	PutIcon	Gets icon from resource file, and draws on screen
	TapeAxes	Draws axes in info window
	AxesTitle	Draws titles on axes in info window
	PixCountTitle	Draws headers for info window
BTiffGraphics4	LoadStats	Calculates total load and area in circle & displays in new window: enables histogram to be saved as ASCII file
	GetCal	Gets and puts clibration data into resource file
BTiffPrint	PrintPort	Prints dithered image & info window
BTiffMainLoop	Main Loop	Awaits an event, and directs to appropriate action: loops until finished flag setby keyboard event

BTiffMain	Main	Sets up memory zone: optional debugging/profiling routines.
-----------	------	--

Figure A2.1 Units and externally-declared procedures within the PBG programme.
Internal procedures and functions are not listed.

PBG Menus

Apple	File	Edit	Circle	Display	Calibration
..	New	<i>Undo</i>	Profiles	✓ Autoiris	Pressure
	Open	<i>Cut</i>	Averages	Pixels (mm)	Spatial
	Close	<i>Paste</i>	On (Off)	Intensity (Pressure)	
	Save	<i>Clear</i>		Load Stats	
	<i>Save as</i>				
	Page setup				
	Print				
	Quit Q				

Figure A2.2 .The above chart indicates the menu options in PBG. Options in italic print are not implemented. A tick before the option indicates a toggle on/off action. Options which change(toggle) on selection are indicated in brackets.

Flow Charts

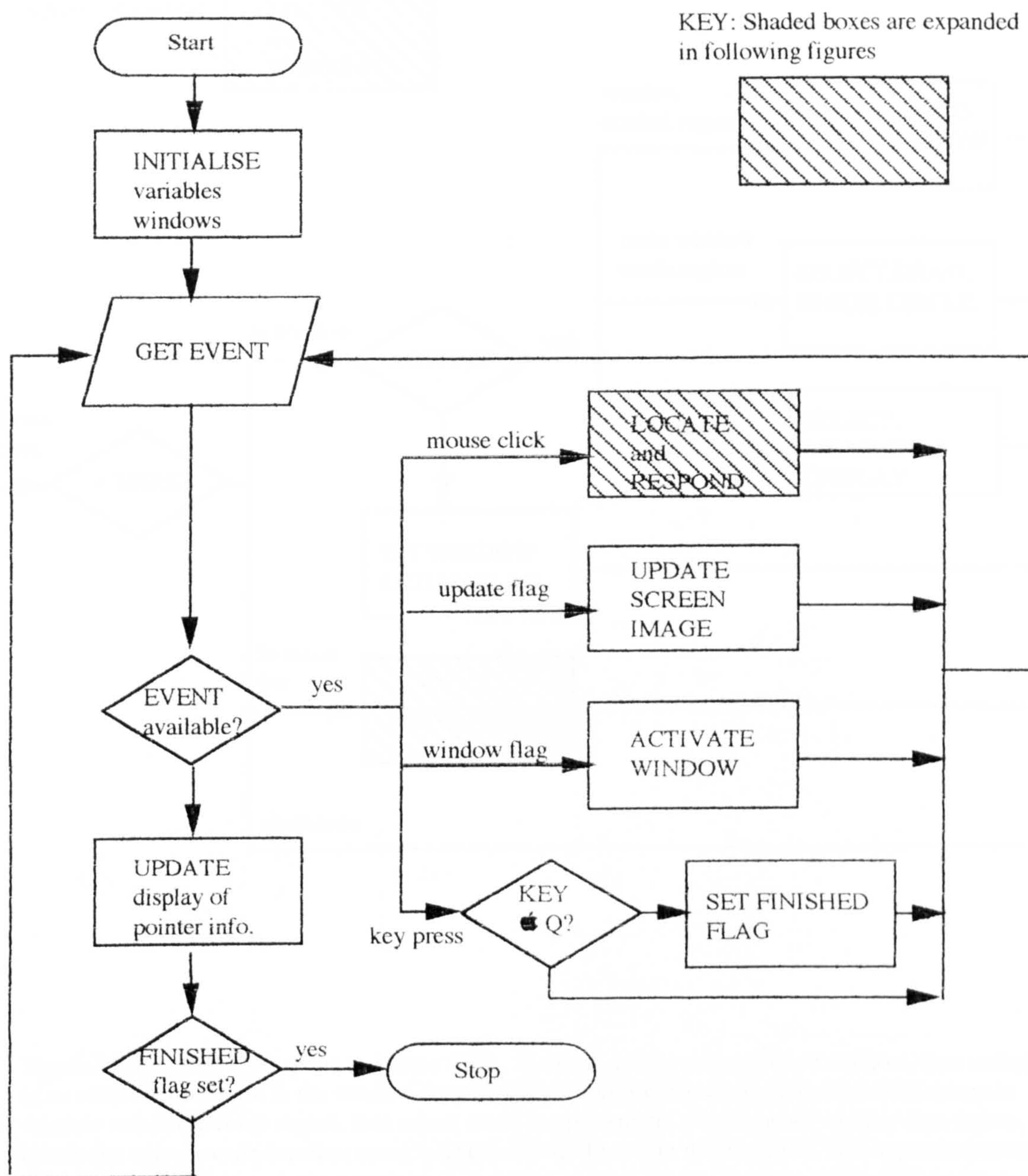


Figure A2.3 Main Loop. The programme continues around the main loop until an event (ie. any user input from keyboard or mouse, or a flag set by a previous action to update the screen image or activate a window) is available in the event queue: this is then enacted. Window activation causes the appropriate window to become 'active': screen update causes all areas accumulated in the 'dirty' register to be redrawn: key input is only used to enabled quitting: the mouse actions are described in the following figures.

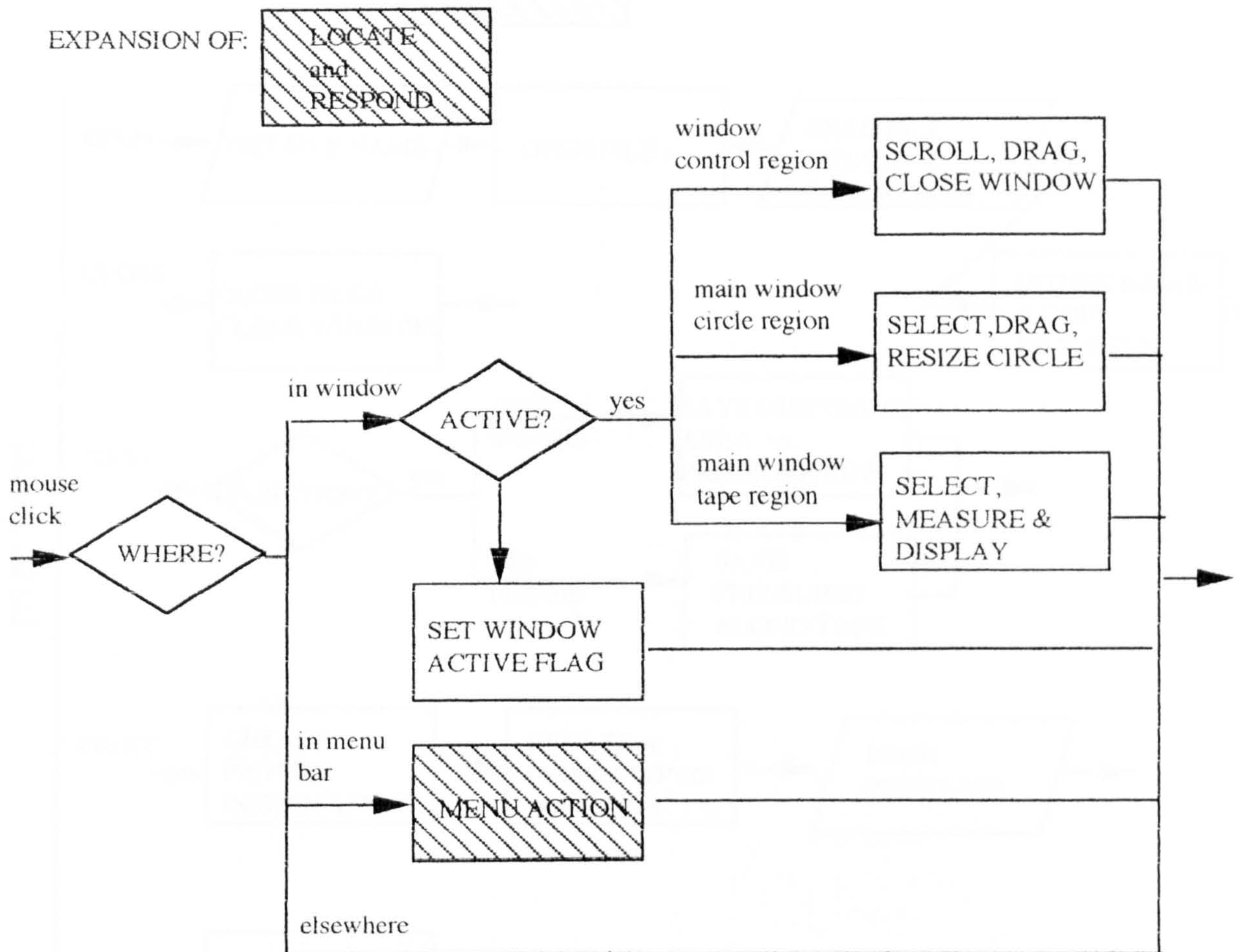
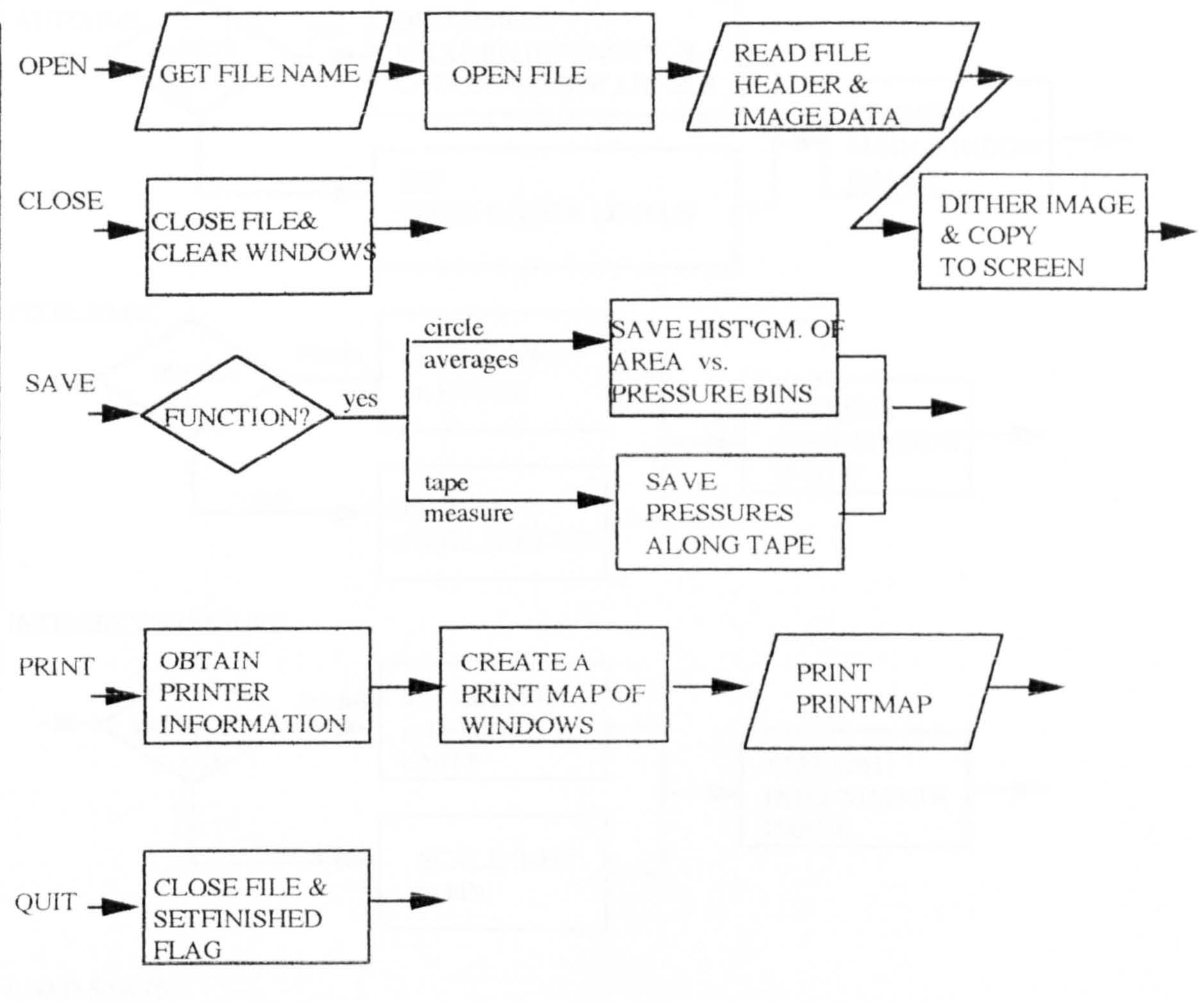


Figure A2.4. Locate & Respond to Mouse Click. If the click is in a de-activated window, then activate: if in an active window and in the window control regions adjust window as appropriate: if in the main window and in the circle region, then adjust circle as appropriate: if in the main window tape region, then enable the tape measure function along a rubber-banded line: if in the menu bar, take appropriate action as indicated in next figure. Actions such as circle adjustments and tape measures will automatically cause updates of the information window display during progress, and will set the screen update flags to cause a redraw of the main window on return to main loop.

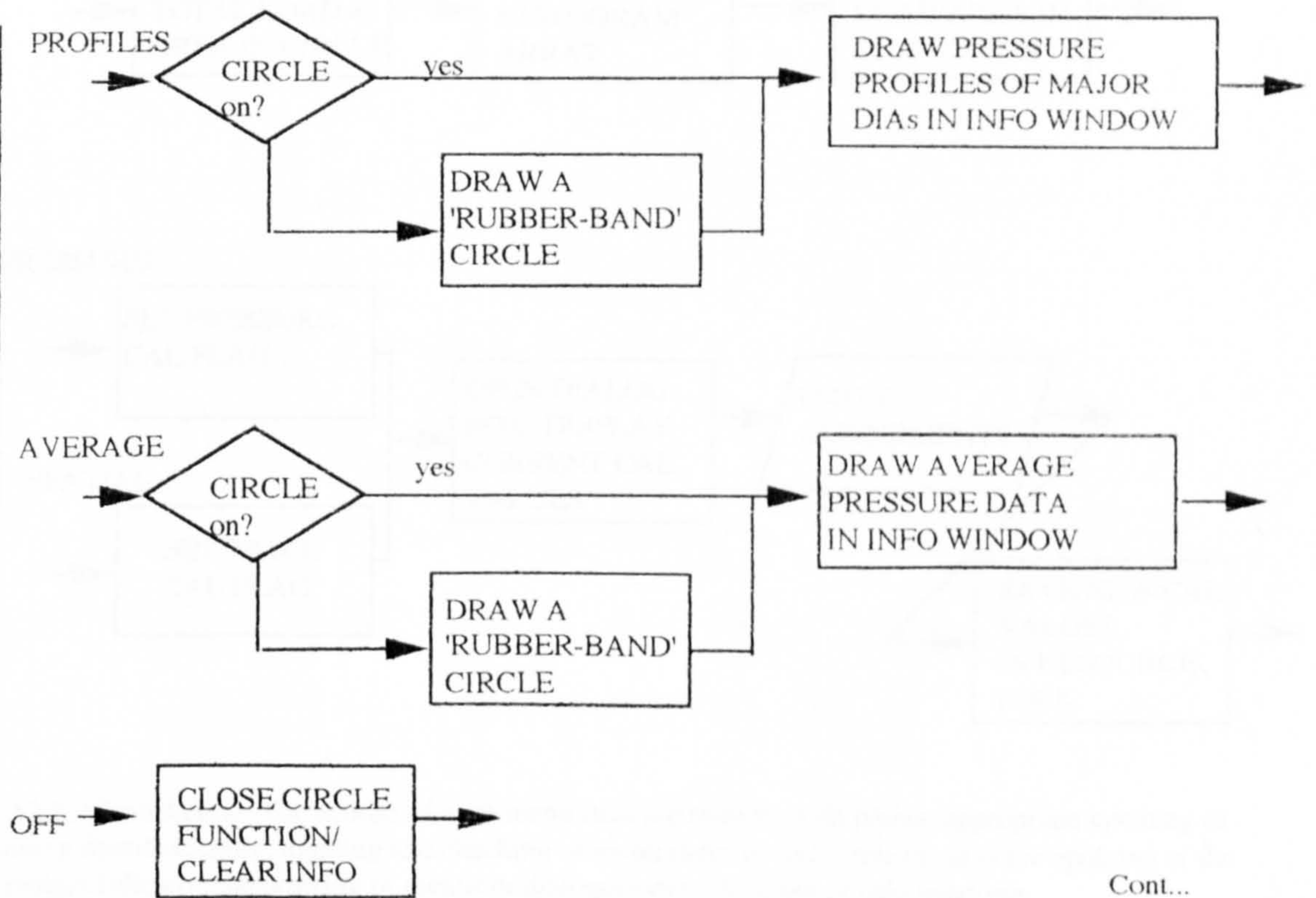
EXPANSION OF:



FILE



CIRCLE



Cont...

Menu Action Cont...

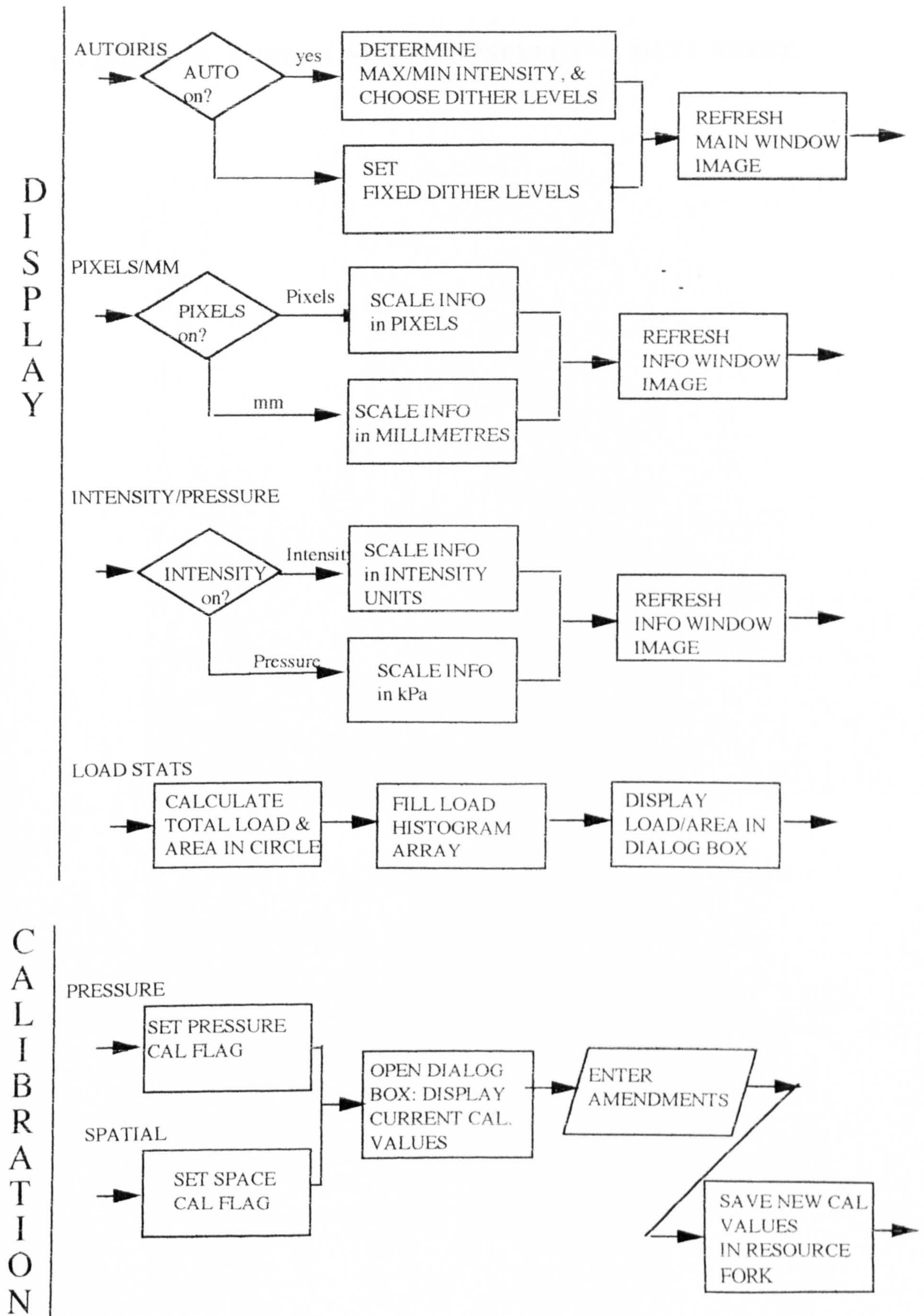


Figure A2.5. Menu Action. The actions of each menu item are shown: at all points, appropriate updating of the dimming & emboldening, toggling and checking of menu items is taken care of, as is the updating of the screen images following the drawing of menus or dialogues over the main or info windows.

APPENDIX III. EUREKA PROJECT "SELECT" .. DATA SHEET.



ORTHOPAEDIC FOOTWEAR: HI-TECH AND FASHIONABLE

As surgical procedures continue to evolve in the West, conditions, which in the past might have led to amputation or early death, such as diabetes, are leaving an increasing number of patients in need of special shoes. In the United Kingdom alone, an estimated 70,000 pairs of special orthopaedic shoes are made each year for patients with foot problems ranging from congenital deformity to arthritis.

Unlike the fashion shoe industry, the orthopaedic footwear industry has not taken advantage of modern technology. Consequently, the craft production methods used are slow. Doctors are frustrated by the variable quality of fit, and patients are frequently disappointed by the lack of modern

styling, which draws attention to their feet. EUREKA project EU 661 intends to help overcome these difficulties by examining the feasibility of an integrated system for the computer-aided design and manufacture of orthopaedic footwear.

Computers bring fashion to orthopaedic shoes

The project - named SELECT - brings together medical researchers and specialist orthopaedic footwear companies from the United Kingdom and the Netherlands. Collaborating with them will be a software development team from Clarks Shoes, a major British shoe manufacturer whose

EUREKA



specialist CAD/CAM system, Shoemaster, is already in use by the fashion shoe trade in a number of countries. SELECT will focus on the definition of the information gathering and information handling requirements of the orthopaedic system. The participants have identified this aspect as holding the key to a cost-effective solution, which will enable maximum use to be made of available measuring and manufacturing equipment.

Clarks Shoes' existing CAD system enables designers to style shoes for the mass market in three dimensions on screen, and provides for computer-controlled cutting and stitching of leather pieces for their upper parts. A standard last, or shoe-former, is used by the computer as the foundation of each design. This last may be scaled to accommodate different sizes or widths of foot, but cannot otherwise be modified.

The system envisaged by the SELECT team will add the ability to apply a shoe design to non-standard lasts. Using measurements of the patient's foot, the system will select the best fit from a small library of digitised lasts representing a range of abnormal foot shapes. Scaling and custom modification of the computer model will allow an individual last to be developed and stored for each patient. Patients will then be able to choose up-to-the-minute designs from a parallel library of shoe styles, which will be married by the computer with their individual last to guarantee a perfect fit every time new shoes are ordered.

The 'magical effects' of collaboration

The SELECT project is being coordinated by the Department of Medical Engineering at King's College School of Medicine in London. Marilyn Lord, Lecturer in Engineering Design at the Department, believes that everyone will gain: "The specialist shoemakers know that they have got to change, and have enthusiastically embraced our project. The Department of Health here in the United Kingdom will benefit from consistently high quality shoes at current or lower prices. And the addition to Shoemaster of an orthopaedic capability will give Clarks a competitive advantage in the international market for CAD/CAM footwear systems."

However the most important benefit, Ms Lord believes, will be to patient care. "Clinicians will welcome the reduced wait for finished shoes and the improved rate of first-time fit. The patients themselves will get a tremendous psychological boost from wearing shoes in the same designs as everyone else. In a limited trial, we fitted children with specially made shoes in high-street fashion styles, and the effects were magical!"

The EUREKA framework has played a vital role in identifying and bringing together partners with the varied expertise necessary to get SELECT off the ground. It has given structure and impetus to the overlapping

aims of different groups and according to Marilyn Lord, has helped the partners to clarify the project's key objectives. "We now hope that by the end of the year we will have defined the information needs of the integrated system. We will then know what structure is needed for the last database, what hardware is necessary to implement its measurement and machining elements, and precisely what modifications must be made to the existing software package. The system itself should follow fairly rapidly after that, as the various tasks are assigned to individual partners."

With expressions of interest already received not only from the European specialist footwear trade, but also from developing countries, and from small, non-orthopaedic, bespoke shoemakers, the commercial future of the system seems assured.

Project Profile

EU 661	
Title:	SELECT Feasibility and definition of integrated measurement, databases and computer-aided design for orthopaedic footwear
Announced at:	The Hague 1991
Participants:	<i>The Netherlands -</i> Centrum voor Orthopedietechniek Amsterdam / Hanssen Orthopedische Schoentechniek / Smeets en Zonen B.V. / TNO Centrum voor Leder en Schoenen / Toornend Orthopedische Service B.V. / Wittekamp en Broos Orthopedische Schoentechniek B.V. <i>United Kingdom -</i> King's College School of Medicine and Dentistry Centre of Rehabilitation Engineering / C & J Clark International Ltd / HW Poole & Son Ltd / Camp Ltd
Main Contact:	Ms. Marilyn Lord King's College School of Medicine and Dentistry Tel: +44 81 693 3377 ext. 3178
Estimated Cost:	0.35 MECU (feasibility study)
Time Scale:	1 year (feasibility study)

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